Oggetto: ACCORDO QUADRO MULTIFORNITORE PER LA FORNITURA DI STENT E DISPOSITIVI PER EMODINAMICA - ADESIONE AZIENDALE EX DEL. DEL D.G. N. 592/2023 E N. 512/2024 - LOTTO N. 6 - AGGIORNAMENTO TECNOLOGICO / SOSTITUZIONE - DITTA EPION SRL.

Il Direttore UOC PROVVEDITORATO ED ECONOMATO

A conclusione di specifica istruttoria, descritta nella narrazione che segue, si rappresenta che ricorrono i presupposti finalizzati all'adozione del presente provvedimento, ai sensi dell'art. 2 della Legge n. 241/1990 e s.m.i. e, in qualità di responsabile del procedimento, dichiara l'insussistenza del conflitto di interessi, ai sensi dell'art. 6bis della legge 241/90 e s.m.i

PREMESSO CHE

- So.re.sa. S.p.A. con Determinazione del Direttore Generale n. 233 del 15/11/2022 ha aggiudicato la "*procedura aperta per la conclusione di un Accordo Quadro Multifornitore per la fornitura di Stent e Dispositivi per Emodinamica* occorrenti alle AA.SS. della Regione Campania;
- con Deliberazione del D.G. n. 592 del 26/06/2023, qui integralmente richiamata e trascritta, questa Aorn ha aderito all'Accordo Quadro SO.RE.SA S.p.A. per la fornitura triennale di Stent e Dispositivi per Emodinamica, aderendo, tra l'altro al lotto 6 "Valvola aortica Ballon Expandable: Bioprotesi valvolare aortica su supporto metallico per impianto transcatetere (vascolare o transapicale) espandibile con pallone, completa di tutti gli accessori richiesti per la preparazione e l'impianto", in capo alla ditta Edwards, quale seconda graduata nella misura del 40%, per una quantità pari a n. 120 unità;
- con successiva delibera n. 512/2024 (agli atti) la stessa Aorn ha proceduto ad integrare l'adesione prestata per il medesimo lotto, per la parte in capo alla Ditta Epion Srl prima graduata nella misura del 60% del lotto (*rect:* 72 unità);

RILEVATO CHE

- la SO.RE.SA., con nota Prot. n. 15201 del 21/05/2024 (allegato n. 1) - relativamente alla fornitura di che trattasi - ha autorizzato, previa richiesta della Ditta EPION S.R.L. (**Allegato 1**), la sostituzione del:

  - Sistema MYVAL INCEPTION –THV in **MYVAL OCTACOR THV** come di seguito specificato:

THV Diametro (mm)	Myval INCEPTION THV Codici offerti in gara	Myval OCTACOR THV Nuovi codici
20	MVLI2200	MOCTA2200
21.5	MVLI2215	MOCTA2215
23	MVLI2230	MOCTA2230
24.5	MVLI2245	MOCTA2245
26	MVLI2260	MOCTA2260
27.5	MVLI2275	MOCTA2275
29	MVLI2290	MOCTA2290
30.5	MVLI2305	MOCTA2305
32	MVLI2320	MOCTA2320

- Val De Crimpt in **CrocoDial Compass** come di seguito specificato:

Val De Crimp Codici offerti in gara	CrocoDial Compass Nuovi Codici
VLDC	CCDC2

CONSIDERATO CHE "*l'aggiornamento tecnologico - sostituzione*" di che trattasi non comporta alcuna spesa aggiuntiva per l'Azienda, rimanendo invariate le condizioni economiche e di fornitura;
RITENUTO, pertanto, di prendere atto della richiesta di *aggiornamento tecnologico – sostituzione*, autorizzata dalla SORESA S.p.A. (già Allegato n.1) - proposta dalla Ditta EPION S.R.L., aggiudicataria del Lotto n. 6 della "*Procedura aperta per la conclusione di un accordo quadro multifornitore per la fornitura di stent e dispositivi per emodinamica occorrenti alle AA.SS. della Regione Campania*", come riportato in premessa e qui integralmente trascritto;
ESAMINATA tutta la documentazione innanzi richiamata allegata alla presente ed in atti giacente;
ATTESTATO CHE la presente determinazione è formulata previa istruttoria ed estensione conformi alla normativa legislativa vigente in materia;

DETERMINA

per le causali in premessa, che qui si intendono integralmente richiamate e trascritte, di:
I - PRENDERE ATTO – relativamente alla fornitura in questione, della richiesta di aggiornamento tecnologico – sostituzione, autorizzata dalla SORESA S.p.A. (già Allegato n.1) - proposta dalla Ditta EPION S.R.L., aggiudicataria del Lotto n. 6 della "Procedura aperta per la conclusione di un accordo quadro multifornitore per la fornitura di stent e dispositivi per emodinamica occorrenti alle AA.SS. della Regione Campania", come riportato in premessa e qui integralmente trascritta;
II – PRECISARE CHE la sostituzione e l'aggiornamento tecnologico in parola non comporta alcuna spesa aggiuntiva per l'Azienda, restando invariate le condizioni economiche e di fornitura;
III - TRASMETTERE copia del presente atto al Collegio Sindacale, come per legge, ed alle UU.OO.CC. Farmacia Ospedaliera e Cardiochirurgia.

L'Estensore
Dott.ssa Maria Cioffi

Il Direttore UOC Provveditorato ed Economato
Dr.ssa Teresa Capobianco

21/05/2024 13.31-20240015201

ALLEGATO 1

SoReSa

L' art. 23 del Codice dell'Amministrazione Digitale (Decreto Legislativo 7 marzo 2005, n. 82 e s.m.i.), riconosce alle copie analogiche di documenti informatici (es. la stampa di un certificato, un contratto, ecc.) la stessa efficacia probatoria dell'originale informatico da cui sono tratti se la loro conformit non viene espressamente disconosciuta (in giudizio). Diverso il caso in cui la conformit all'originare informatico, in tutte le sue componenti, sia attestata da un pubblico ufficiale autorizzato. In questo caso, infatti, per negare alla copia analogica di documento informatico la stessa efficacia probatoria del documento sorgente si rende necessaria la querela di falso.

Questo regime, di carattere generale, incontra alcune deroghe rispetto alle copie analogiche di documenti amministrativi informatici.

L'art. 23-ter del CAD prevede che sulle copie analogiche di documenti amministrativi informatici possa essere apposto un contrassegno a stampa (detto anche timbro digitale o glifo) che consente di accertare la corrispondenza tra le copie analogiche stesse e l'originale informatico (in esso deve essere codificato, infatti, il documento informatico o le informazioni necessarie a verificarne la corrispondenza all'originale in formato digitale). La verifica avviene grazie ad appositi software che leggono le informazioni contenute nel timbro digitale. I software necessari per l'attivit di verifica devono essere gratuiti e messi liberamente a disposizione da parte delle amministrazioni.

Copia conforme di un documento amministrativo informatico formata ai sensi dell'articolo 23-ter, comma 5 del CAD.
Il presente contrassegno digitale Datamatrix contiene informazioni utili alla verifica della corrispondenza del documento all'originale digitale conservato dall'amministrazione proprietaria dello stesso.
Il contrassegno pu essere letto con qualsiasi applicazione in grado di decodificare il formato Datamatrix e con gli smartphone dei principali costruttori.
In alternativa possibile collegarsi al sistema DgsWebOS dell'amministrazione e ricercare dopo l'autenticazione il documento

Impronta del documento digitale originale: 12f485bec75317f03f669774cb64b7c5
Identificativo del documento digitale originale: 574206
Protocollo: SoReSa-0007804-2024 21-05-2024 10:33:31

Documento generato dal sistema DgsWebOS in data: 21-05-2024 10:47:48

Società Regionale per la Sanità S.P.A.

Ai Sig.ri Direttori Generali
Ai Sig.ri Provveditori
AA.SS.LL., AA.OO., AA.OO.UU., IRCSS
a mezzo pec

e p.c.

EPION SRL
A mezzo pec: : epionsrl@gigapec.it

Oggetto: Autorizzazione aggiornamento tecnologico- Procedura aperta per la Conclusione di un Accordo Quadro per l'affidamento della "Fornitura di Stent e Dispositivi per Emodinamica" occorrenti alle AA. SS. della Regione Campania. LOTTO 6

Con riferimento alla procedura in oggetto

vista la richiesta di autorizzazione aggiornamento tecnologico- sostituzione presentata dalla società EPION SRL nell'ambito della suddetta fornitura in data 15/04/2024

alla luce dell'istruttoria espletata ed acquisito il parere tecnico favorevole circa l'aggiornamento tecnologico proposto dalla Ditta

si autorizza, secondo le previsioni del Capitolato Tecnico di gara, alle medesime condizioni economiche contrattuali, l'aggiornamento tecnologico- sostituzione come da richiesta che costituisce parte integrante e sostanziale della presente.

In allegato:

- Istanza di autorizzazione aggiornamento tecnologico.
- Documentazione tecnica.

Distinti saluti.

So.Re.Sa. S.p.A.
Il Responsabile dell'esecuzione dei contratti
Avv. Gianmarco Massa

Avv. Fabio Aprea
Direttore Affari Legali

epion

Spett.le Soresa

Oggetto: ***Procedura aperta per la Conclusione di un Accordo Quadro per l'affidamento della "Fornitura di Stent e Dispositivi per Emodinamica" occorrenti alle AA. SS. della Regione Campania. LOTTO 6***

Comunicazione di ridenominazione del sistema MYVAL INCEPTION-THV in MYVAL OCTACOR-THV e aggiornamento tecnologico del dispositivo di crimpatura.

La sottoscritta Giulia Matteoli nata a Roma (RM) il 12/04/83 in qualità di Amministratore unico della società Epion Srl con sede in Napoli, Via S. Giacomo dei Capri n.52, C.F. e P. IVA 03267410920, iscritta alla CCIAA di NAPOLI al numero 03267410920, PEC: epionsrl@gigapec.it

COMUNICA

- Che per motivi commerciali, la denominazione del Sistema MYVAL INCEPTION-THV è stata modificata in **MYVAL OCTACOR THV**. Pertanto, si chiede la sostituzione dei codici offerti in gara come di seguito specificato:

THV Diametro (mm)	Myval INCEPTION THV Codici offerti in gara	Myval OCTACOR THV Nuovi Codici
20	MVLI2200	MOCTA2200
21.5	MVLI2215	MOCTA2215
23	MVLI2230	MOCTA2230
24.5	MVL12245	MOCTA2245
26	MVLI2260	MOCTA2260
27.5	MVL12275	MOCTA2275
29	MVLI2290	MOCTA2290
30.5	MVLI2305	MOCTA2305
32	MVLI2320	MOCTA2320

- che Val De Crimp è stato dismesso in Europa ed è stato sostituito con uno strumento di crimpatura di nuova generazione, **CrocoDial Compass**. Pertanto, si chiede la sostituzione del codice offerto in gara come di seguito specificato:

Val De Crimp Codici offerti in gara	CrocoDial Compass Nuovi Codici
VLDC	CCDC2

Sede Legale/Commerciale
Via San Giacomo dei Capri 52 · 80128 · Napoli · C.F./Piva 03267410920 · Tel +39 06 62289334 · Fax +39 06 92932164

Sede Operativa
Via Antiniana 2/C · 80078 · Pozzuoli (NA) · amministrazione@epion.care · epion.care

Si allega documentazione tecnica e comunicazione ricevuta dal produttore.

Napoli, 15.04.2024

EPION S.R.L.
Giulia Matteoli
Legale Rappresentante
(FIRMA DIGITALE)

Sede Legale/Commerciale
Via San Giacomo dei Capri 52 · 80128 · Napoli · C.F./Piva 03267410920 · Tel +39 06 62289334 · Fax +39 06 92932164
Sede Operativo
Via Antiniana 2/G · 80078 · Pozzuoli (NA) · amministrazione@epion.care · epion.care

8th April 2024

To,

Epion Srl.

Via Antiniana 2/G, 80078 Pozzuoli (NA), Italy

Subject: Notification of Brand Name Change of Myval INCEPTION -THV system to Myval Octacor- THV System

Dear Giulia,

This letter is with reference to brand name change of Myval INCEPTION THV system to Myval OCTACOR THV system.

Further, in context to the So.Re.Sa Tender (Campania Regional Tender), we would like to inform that at the time of tender application the balloon expandable THV of Meril, the application was under the brand name Myval INCEPTION THV System.
Subsequently, due to commercial reasons, the brand name of the THV was changed to Myval OCTACOR THV System. This change was assessed and approved by the European Notified Body.

We hereby confirm that both Myval INCEPTION THV and Myval OCTACOR THV are same products (different brand names) and there are no technical changes.

Meril will supply Myval OCTACOR THV instead of Myval INCEPTION THV with following codes-

THV Diameter (mm)	Myval INCEPTION THV Codes	Myval OCTACOR THV Codes
20	MVLI2200	MOCTA2200
21.5	MVLI2215	MOCTA2215
23	MVLI2230	MOCTA2230
24.5	MVLI2245	MOCTA2245
26	MVLI2260	MOCTA2260
27.5	MVLI2275	MOCTA2275
29	MVLI2290	MOCTA2290
30.5	MVLI2305	MOCTA2305
32	MVLI2320	MOCTA2320

We would also like to Notify that, we have discontinued with Val De Crimp (VLDC) and Val De Crimp Neo (VLDCN) in Europe. We have replaced the devices with a new generation Crimping tool CrocoDial Compass (CCDC2).

We trust this will help resolve any confusion and remain available for clarifications.

Authorized Signatory.

Narendra Patel,
Head Quality Assurance and Regulatory Affairs
Meril Life Sciences Pvt. Ltd.

MERIL LIFE SCIENCES (P) LTD. VAPI

8th April 2024

To,

Epion Srl.

Via Antiniana 2/G, 80078 Pozzuoli (NA), Italy

Oggetto: Notifica di ridenominazione del sistema Myval INCEPTION -THV in Myval Octacor-THV System

Cara Giulia,

La presente per comunicare la modifica di denominazione del sistema Myval INCEPTION THV in **Myval OCTACOR THV.**

Inoltre, nell'ambito della Gara So.Re.Sa (Gara Regionale Campania), si informa che al momento della presentazione della gara il palloncino espandibile THV di Meril era a marchio Myval INCEPTION THV System.

Successivamente, per motivi commerciali, il marchio della THV è stato cambiato in Myval OCTACOR THV System. Questa modifica è stata valutata e approvata dall'Organismo Notificato Europeo.

Con la presente confermiamo che Myval INCEPTION THV e Myval OCTACOR THV sono prodotti uguali (marchi diversi) e non ci sono modifiche tecniche.

Meril fornirà Myval OCTACOR THV invece di Myval INCEPTION THV con i seguenti codici

THV Diametro (mm)	Myval INCEPTION THV Codici	Myval OCTACOR THV Codici
20	MVLI2200	MOCTA2200
21.5	MVLI2215	MOCTA2215
23	MVLI2230	MOCTA2230
24.5	MVL12245	MOCTA2245
26	MVLI2260	MOCTA2260
27.5	MVL12275	MOCTA2275
29	MVLI2290	MOCTA2290
30.5	MVLI2305	MOCTA2305
32	MVLI2320	MOCTA2320

Si notifica, inoltre, la dismissione di Val De Crimp (VLDC) e Val De Crimp Neo (VLDCN) in Europa. I dispositivi sono stati sostituiti con uno strumento di crimpatura di nuova generazione, **CrocoDial Compass** (CCDC2).

Confidiamo che questo aiuterà a risolvere qualsiasi confusione e rimaniamo a disposizione per chiarimenti.

Timbro e Firma

Meril Life Science Pvt. Ltd.. CIN: U24230GJ2008PTC055213
Muktanand Marg, Chala, Vapi 396191 Telephone No: +91 260 2408 000, FAX: +91 260 2408025,
Email ID: askinfo@merillife.com, Website: www.merillife.com

IMMIGRATION INDIA
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24 NOV 2023
ARRIVAL
CSMI AIRPORT, MUMBAI

भारत गणराज्य REPUBLIC OF INDIA

प्रकार / Type: P
राष्ट्र कोड / Country Code: IND
पासपोर्ट सं. / Passport No.: T3096461

उपनाम / Surname: PATEL

दिया गया नाम / Given Name(s): NARENDRAKUMAR BABUBHAI

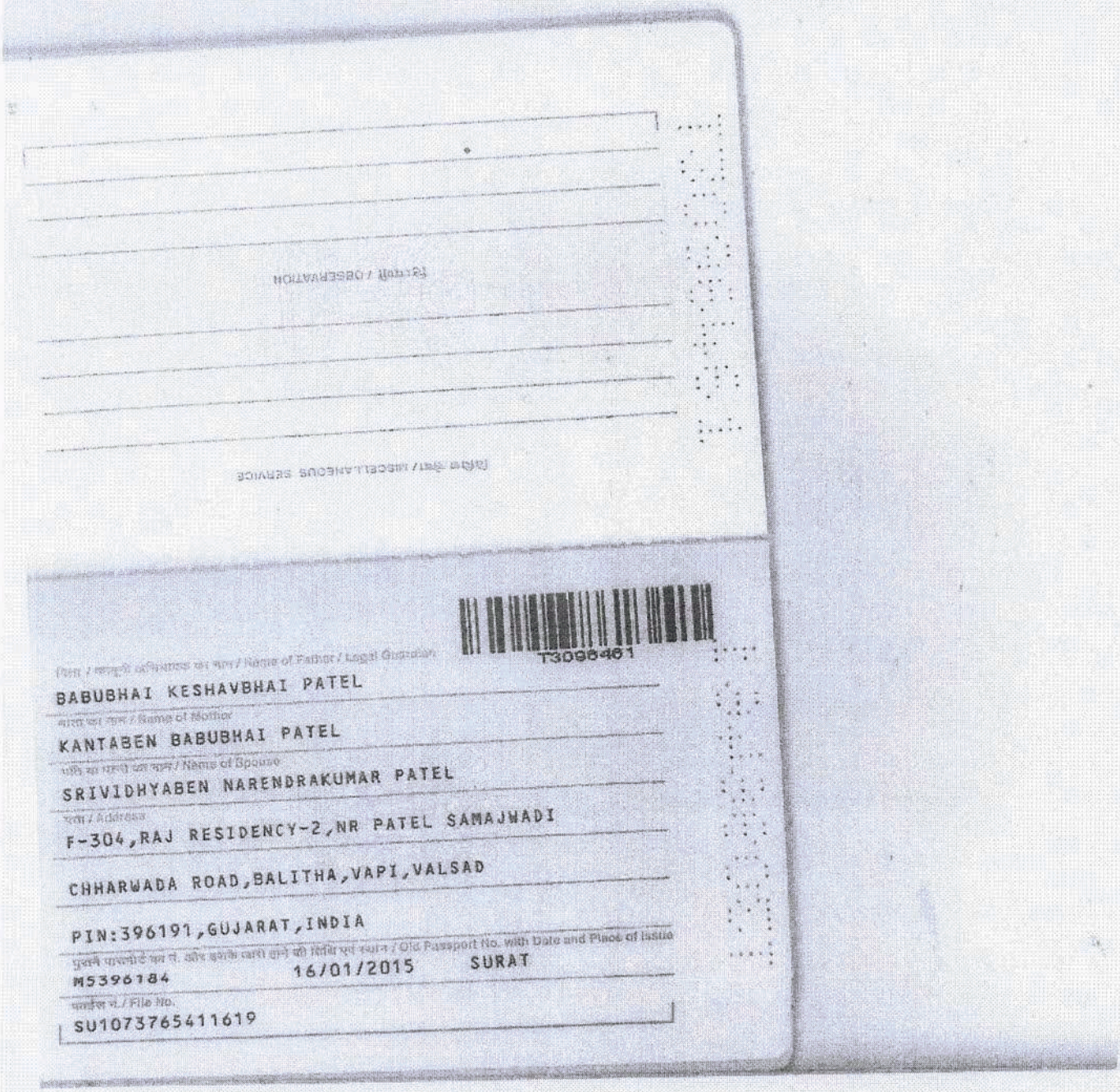
राष्ट्रीयता / Nationality: भारतीय/INDIAN
लिंग / Sex: M
जन्म तारीख / Date of Birth: 17/09/1980

जन्म स्थान / Place of Birth: AHMEDABAD,GUJARAT

जारी करने का स्थान / Place of Issue: SURAT

जारी करने की तिथि / Date of Issue: 12/06/2019
समाप्ति की तिथि / Date of Expiry: 11/06/2029

P<INDPATEL<<NARENDRAKUMAR<BABUBHAI<<<<<<<<<<
T3096461<2IND8009179M2906117<<<<<<<<<<<<<<<2



T3096461

पिता / संरक्षक का नाम / Name of Father / Legal Guardian
BABUBHAI KESHAVBHAI PATEL

माता का नाम / Name of Mother
KANTABEN BABUBHAI PATEL

पति या पत्नी का नाम / Name of Spouse
SRIVIDHYABEN NARENDRAKUMAR PATEL

पता / Address
F-304,RAJ RESIDENCY-2,NR PATEL SAMAJWADI

CHHARWADA ROAD,BALITHA,VAPI,VALSAD

PIN:396191,GUJARAT,INDIA

पुराने पासपोर्ट का नं. और इसके जारी होने की तारीख एवं स्थान / Old Passport No. with Date and Place of Issue
M5396184 16/01/2015 SURAT

फाईल नं. / File No.
SU1073765411619

Sistema di crimpaggio Crocodial compass per valvole cardiache transcatetere Myval™Octacor

Ditta produttrice:	Meril Life Sciences Pvt. Ltd. Muktanand Marg, Chala, Vapi – 396191. Gujarat. India.
Marchio CE:	Il dispositivo medico è conforme alla Direttiva 93/42 CEE • Marchio CE 1434-MDD-159/2021 -1434-POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. (PCBC)
Classe di appartenenza:	Classe I
Codice CND	P0780 - PROTESI VASCOLARI E CARDIACHE - ACCESSORI
N. di Repertorio	2326538 per codice CCDC
	2400552 per codice CCDC2
Presenza/Assenza lattice	Prodotto PRIVO DI LATTICE (LATEX FREE)

DESCRIZIONE DEL DISPOSITIVO

Crocodial Compass™ è un dispositivo per il crimpaggio delle valvole cardiache transcatetere **Myval™ Octacor** con catetere Navigator™Inception.

Meccanismo di compressione, sterile, per ridurre con precisione il diametro del palloncino espandibile per l'impianto delle valvole cardiache transcatetere Myval Octacor™(Figura 1).

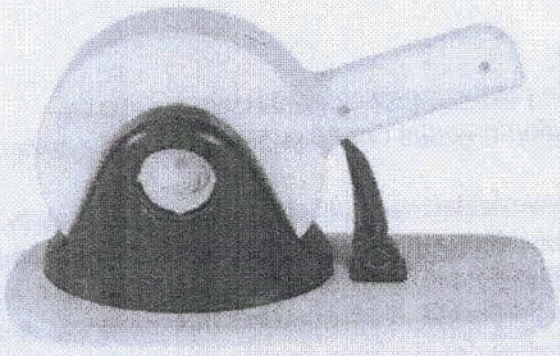


Figura 1 – Crocodial Compass™

DESTINAZIONE D'USO

Crocodial Compass™ è uno strumento indicato per l'impianto delle valvole cardiache transcatetere **Myval Octacor™.**

INDICAZIONE

Il sistema di crimpaggio Crocodial Compass™ è destinato alla crimpatura delle valvole cardiache transcatetere **Myval Octacor™.**

ELENCO DEI COMPONENTI E DEI MATERIALI INCORPORATI NEL SISTEMA DI CRIMPAGGIO CROCODIAL COMPASS™

I materiali utilizzati per la produzione di Crocodial Compass™ sono elencate nella seguente Tabella:

Componente	Materiale
PIASTRA BASE	Polyamide 6 / fibra di vetro
CORPO (destro e sinistro)	Acrylonitrile butadiene Styrene (ABS)
GUIDA PIASTRA (destro e sinistro)	Acrylonitrile butadiene Styrene (ABS)
MANICO (destro e sinistro)	Acrylonitrile butadiene Styrene (ABS)
FERMO BASE	Acrylonitrile butadiene Styrene (ABS)
FERMO	Acrylonitrile butadiene Styrene (ABS)
JAW (segmento) 1,2 e 3	Poliossimetilene (POM-H)
MATERIALI CONFEZIONE	
CONFEZIONE INTERNA	Tyvek 1073B
CONFEZIONE ESTERNA	Tyvek 1073B/LLDPE
SCATOLA	CARTONE CORRUGATO

IMBALLAGGIO

Imballaggio generale

L'imballaggio primario risulta essere a doppia barriera sterile.

Il sistema di crimpaggio Crocodial Compass™ è posizionato nella busta rivestita TYVEK 1073B sigillata a caldo.

Questi sacchetti di tyvek sigillati sono ulteriormente posizionati in una seconda confezione.

La confezione è termosaldata. Un'etichetta di identificazione è apposta sulla busta.

Questo forma l'imballaggio primario di Crocodial Compass™ ed il prodotto confezionato primario è sterilizzato ad Ossido di etilene mediante processo di sterilizzazione ETO. Dopo la sterilizzazione, le etichette del prodotto finale vengono apposte sulla rispettiva confezione e sono imballati in una scatola esterna insieme alle informazioni per l'uso (IFU),e sacchetto assorbitore di umidità.

La scatola esterna è sigillata con l'etichetta "QA approved" ed è un prodotto finito

L'etichetta con i dettagli del prodotto è apposta sulla scatola esterna. Questa scatola esterna è ulteriormente avvolta da una pellicola in PP.

STERILIZZAZIONE

Crocodial Compass™ è sterilizzato con il metodo della sterilizzazione con ossido di etilene. La sterilizzazione con ossido di etilene è convalidato secondo i seguenti standard:

" Guida ISO 11135-2014 per la sterilizzazione dei prodotti per la salute-Ethylene oxidepart: Requisiti per lo sviluppo, la convalida e il controllo di routine di un processo di sterilizzazione dei dispositivi medici fino alla sterilità livello di garanzia di 10-6".

" ISO 10993-7:2008 per la valutazione biologica dei dispositivi medici - Parte 7: Sterilizzazione a ossido di etilene residui".

" ISO 11138-2:2017 per la sterilizzazione dei prodotti sanitari - Indicatori biologici - Parte 2: Biologici Indicatori per i processi di sterilizzazione con ossido di etilene".

" ISO 11737-1: 2018 per dispositivi medici di sterilizzazione - Metodi microbiologici - Parte 1 Determinazione di popolazione di microrganismi sui prodotti".

"ISO 11737-2:2009 - Sterilizzazione dei dispositivi medici - Metodi microbiologici - Parte 2: Test di sterilità eseguita nella definizione, validazione e manutenzione di un processo di sterilizzazione".

Stoccaggio:

Crocodial Compass™ deve essere conservato in un luogo fresco e asciutto nella sua confezione originale.

SPECIFICHE DEL PRODOTTO

PARAMETRI	
Diametro di apertura in posizione aperta	35 +/- 1 mm
Diametro di apertura in posizione chiusa	2 +/- 1 mm
Diametro corpo principale	151 +/- 2 mm
Larghezza del corpo principale	90 +/- 2 mm

ELENCO MODELLI

DESCRIZIONE	CODICE
CROCODIAL COMPASS™	CCDC/ CCDC2

Meril

Valvola cardiaca transcatetere Myval ™ OCTACOR (THV)

Scheda Tecnica

Ditta produttrice:	Meril Life Sciences Pvt. Ltd. Muktanand Marg, Chala, Vapi – 396191. Gujarat. India.
Marchio CE:	Il dispositivo medico è conforme alla Direttiva 93/42 Marchio CE 1434-MDD-160/2021 Polish Centre for Testing and Certification
Classe di appartenenza:	Classe III
Codice CND:	P0703010302
N° di repertorio:	2323836
Presenza/assenza di lattice:	Prodotto PRIVO DI LATTICE (LATEX FREE)

Myval™ OCTACOR Transcatheter Heart Valve

DESCRIZIONE

Il sistema Myval™ OCTACOR è costituito da una struttura radiopaca Balloon-expandable, in lega di Cromo Nickel Cobalto Molibdeno, da una valvola a tre lembi in pericardio bovino decalcificato e decellularizzato con processi brevettati di proprietà, da un rivestimento interno in polietilene tereftalato (PET) e da un rivestimento esterno in PET (Figura 1).
Myval™ OCTACOR è offerta nei diametri 20mm, 21.5mm, 23mm, 24.5mm, 26mm, 27.5mm, 29mm, 30.5mm, 32mm.

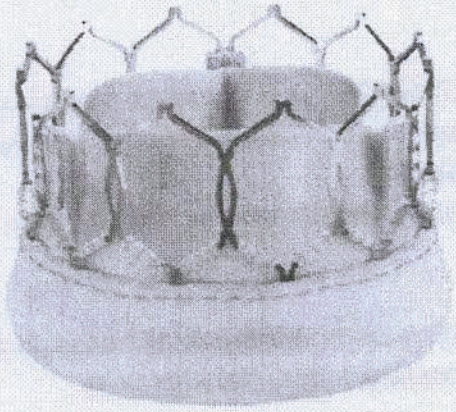


Figura 1

INDICAZIONI

La valvola Myval™ OCTACOR (THV) è indicata per il posizionamento transcatetere in pazienti con stenosi aortica calcifica nativa severa, considerati ad elevato rischio chirurgico.
La valvola Myval™ OCTACOR (THV) è indicata ad essere impiantata in anulus nativo associato all'area misurata all'anello basale durante la sistole (20% R-R) (vedi tabella 1 sotto):

Diametro dell'anulus all'Ecocardiogramma Transesofageo (mm)	Area Anulus nativo (mm^2)	Diametro Area-derivato (mm)	Misura Myval (mm)
16 – 19	270 – 330	18.5 – 20.5	20
17.5 – 20.5	314 – 380	20.0 – 22.0	21.5
18 – 22	360 – 440	21.4 – 23.7	23
19.5 – 23.5	410 – 500	22.8 – 25.2	24.5
21 – 25	460 – 560	24.2 – 26.7	26
22.5 – 26.5	510 – 630	25.5 - 28.3	27.5
24 – 28	570 – 700	26.9 – 29.9	29
25.5 – 29.5	630 – 770	28.3 – 31.3	30.5
27 – 31	700 – 840	29.9 – 32.7	32

Tabella 1

Tutte le misure di Myval OCTACOR sono compatibili con introduttore dedicato Python da 14 Fr grazie alle sue proprietà elastomeriche che consentono l'espansione dell'introduttore durante il passaggio della valvola.
In caso di necessità, è possibile ritirare la valvola non espansa attraverso il lume dell'introduttore da 14 Fr.

Il sistema Myval™ OCTACOR è compatibile con gli accessi transfemorale, transucclavia, transaortico, transcarotideo, transascellare, transapicale.

COMPONENTI E SPECIFICHE DEL MATERIALE MyVal™ OCTACOR

COMPONENTI	MATERIALI
Myval™ OCTACOR Transcatheter Heart Valve	
Frame in metallo	Lega di Nickel Cromo Cobalto Molibdeno
Lembi valvolari	Pericardio bovino
Diametri della Valvola disponibili (mm)	20, 21.5, 23, 24.5, 26, 27.5, 29, 30.5, 32
Altezze della Valvola disponibili (mm)	Da 17.50 a 21.30
Rilascio	Balloon Expandable
Commissure Support Fabric	Cardial Flat Sheet (PET)
Skirt Fabric, Arc Fabric & Cuff Fabric	PET TAPE
Suture bianche	Polyestere Wax bianco
Suture verdi	Polyestere Wax
Dischi	ABS
Gabbia	ABS
Guarnizione (Ring)	Silicone
Contenitore	Polipropilene (PP)
Film termoretraibile	Poly-oly
Confezione	Cartone stampato su film metallizzato a laminazione
Confezione secondaria	Scatola in Polistirene

Tabella 2

ELENCO CODICI CATALOGO

Misura Myval (mm)	Codice Catalogo
20.0	MOCTA2200
21.5	MOCTA2215
23.0	MOCTA2230
24.5	MOCTA2245
26.0	MOCTA2260
27.5	MOCTA2275
29.0	MOCTA2290
30.5	MOCTA2305
32.0	MOCTA2320

Tabella 3

IMBALLAGGIO

1. Imballaggio primario in barattolo in Polipropilene (PP)

Questo processo viene eseguito in camera bianca in classe 100000 sotto LAF (classe 100). La valvola cardiaca transcatetere è temporaneamente cucita sul fondo della gabbia. La gabbia contenente la valvola viene inserita nel barattolo in PP che viene riempito completamente con 0,625 % di glutaraldeide come soluzione di stoccaggio. La gabbia viene coperta posizionando il disco sopra la gabbia. All'interno del coperchio del barattolo viene inserito un anello in silicone e il barattolo viene chiuso ermeticamente con il coperchio. Un'etichetta di identificazione è apposta sul coperchio del vasetto. Questo costituisce l'imballaggio primario della valvola cardiaca Myval™ OCTACOR.

Il vaso in PP contenente la valvola cardiaca Myval™ OCTACOR viene inviato per la sterilizzazione liquida.

2. Imballaggio secondario

Dopo la sterilizzazione il vasetto in PP viene etichettato e inserito nella scatola del prodotto insieme alle informazioni per l'uso (IFU) e le etichette di riferimento. Questa confezione è avvoltaa caldo utilizzando sacchetto in PP.

3. Imballaggio per la spedizione

Formato Codice Prodotto - MVxxx	MOCTA = Myval™ xxx = diametro nominale dello Stent (mm) Esempio, MVL200 xxx = 200 = Diametro 20 mm

Le confezioni sono collocate in un contenitore in polistirolo dove la borsa del ghiaccio viene posizionata nella parte superiore, inferiore e sui quattro lati intorno alla confezione. Il contenitore in polistirolo ulteriormente confezionato all'interno di scatola E – Flute.
Le confezioni vengono poste in una scatola di cartone ondulato (scatola di spedizione) in base alla quantità da spedire. La scatola di cartone ondulato è sigillata con nastro BOPP e l'etichetta di distribuzione è apposta sulla scatola di spedizione.

STERILIZZAZIONE

La valvola Myval™ OCTACOR è sterilizzata con il metodo della sterilizzazione chimica liquida. Il processo di sterilizzazione chimica liquida per Myval™ OCTACOR è convalidato secondo i seguenti standard per un livello di garanzia di sterilità di 10-6:

- ISO 14160: Sterilizzazione dei prodotti sanitari - Agenti chimici sterilizzanti liquidi per dispositivi medici monouso che utilizzano tessuti animali e loro derivati - Requisiti per la caratterizzazione, lo sviluppo, la convalida e il controllo di routine di un processo di sterilizzazione per dispositivi medici.
- ISO 11737-1: Sterilizzazione dei dispositivi medici - Metodi microbiologici - Parte 1: Determinazione di una popolazione di microrganismi sui prodotti
- ISO 11737-2: Sterilizzazione dei dispositivi medici - Metodi microbiologici - Parte 2: Prove disterilità eseguite nella definizione, convalida e mantenimento di un processo di sterilizzazione.

STOCCAGGIO

La valvola cardiaca Myval™ OCTACOR deve essere conservata ad una temperatura compresa tra 10°C e 25°C (50°F e 77°F). Il sistema di consegna e gli accessori devono essere conservati in un luogo fresco e asciutto.

CERTIFICATE

EC Certificate No. 1434-MDD-160/2021
Full Quality Assurance System
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Meril Life Sciences Pvt. Ltd.

Muktanand Marg, Chala, Vapi-396191
Gujarat, India

for the design, manufacture and final inspection of
medical devices, class III

Transcatheter Heart Valve System

Brand names: Myval™-Transcatheter Heart Valve System, Myval™INCEPTION-Transcatheter Heart Valve System, Myval™ Neo Transcatheter Heart Valve System, Myval™ Pro Transcatheter Heart Valve System, Eternis™ Transcatheter Heart Valve System, Merineum™ Transcatheter Heart Valve System, Mavis™ Transcatheter Heart Valve System

The list of medical devices covered by this certificate is provided in the annex to EC Design-examination Certificate No. 1434-MDD-159/2021

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2021-04-01 to 2024-04-08

The date of issue of the Certificate: 2021-04-01

The date of the first issue of the Certificate: 2019-04-09

CE 1434

Issued under the Contract No. **MD-11/2018**
Application No: 088/2021
Certificate bears the qualified signature.
Warsaw, 01/04/2021
Module H2/3/4/5

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.03.31 15:24:42 +02'00'
Vice-President

Meril

DECLARATION OF CONFORMITY

Manufacturer's Name: MERIL LIFE SCIENCES PVT. LTD.

Manufacturer's Address: Muktanand Marg, Chala, Vapi – 396191, Gujarat, India.

Product Name: Myval™ OCTACOR - Transcatheter Heart Valve System

Product Details:

GMDN Code:	60245	Control No.:	DOC/MOCTA2/Rev.00/24.06.2022
Batch No.:	_____	Mfg. Date:	_____
Batch Released Quantity:	_____	Expiry Date:	_____

Conforms to the applicable national/ international Standards.

1. We declare that our products as listed below, comply with the requirements to Medical device Directive 93/42/EEC as amended by directive 2007/47/EC, Commission Regulation (EU) No. 722/2012 of 8 August 2012, Annex I and this declaration is sole responsibility of company.

A. **Myval™ OCTACOR - Transcatheter Heart Valve System. It includes following components.**

- Transcatheter Heart Valve. (Trade Name: Myval™ OCTACOR)
- Transcatheter Heart Valve Delivery System. (Trade Names: Navigator™ /Navigator Neo™/Navigator Pro™/ Navigator™ Inception/ Navigator™ RONDEVU)
- Balloon Dilatation Catheter. (Trade Names: Mammoth™/ Mammoth Neo™)
- Introducer Set. (Trade Name: Python™/ Python™ Pro/ Python™ Inception/ Python™ Novela)
- Crimping Tool
  - Transcatheter Heart Valve Crimping Tool (Sterile) (Trade Names: Val-de-Crimp™/ CrocoDial Compass™)
  - or
  - Transcatheter Heart Valve Crimping Tool (Non-sterile) (Trade Name: CrocoDial™)

2. Company undertakes to manufacture the products as per National/ International Standards and following quality management system as per ISO 13485:2016/ NS-EN ISO 13485:2016.
3. Company authorizes the notified body to carry out necessary inspection and agrees to supply the required information & data/documents from time to time.
4. Company agrees to make available all relevant Documents & Data of the products to the National and competent Authority for a period ending 15 (Fifteen) years after the last product has been manufactured.
5. Company or his authorized representative shall fulfill the obligations imposed by Annex II (Full Quality Assurance system) of Medical Device Directive 93/42/EEC as amended & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.
6. Company undertakes to keep up to date a systematic procedure to review experience gained during post production phase and to implement appropriate means to apply any necessary corrective action taking account of the nature & risk in relation to the product.
7. Company undertakes to notify immediately any malfunction /deterioration of the performance of the device to the appropriate authority and shall recall such devices already placed in the market.
8. Company shall fulfill the obligations imposed by Annex I of Medical Device Directive 93/42/EEC as amended & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.
9. Company declares that Myval™ OCTACOR -Transcatheter Heart Valve System contains material of animal tissue derivative.

List of Standard Applied: MDD/93/42/EEC as amended by Directive 2007/47/EC, EN ISO 13485:2016/AC:2016/AMD 2018, ISO 13485-2016/A11:2021, EN ISO 5840:2015, EN ISO 5840-3:2013, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO-25539-2:2012, EN 1041:2008, EN ISO 10555-1-2013+A1:2017, EN ISO 10555-4:2013, EN ISO 10993-1:2020, EN ISO 14160 – 2011, EN ISO 11135-2014/AMD 1:2018, EN ISO 11607-1:2020. EN ISO 22442-1-2015, EN ISO 22442-2-2015, EN ISO 80369-1:2018, EN ISO 11070:2014/A1:2018, ICH Q1A (R2), ASTM F 1980-2016, ASTMF 2097-11(2019), MDD 93/42/EEC/1993, EU MDR 2017/745, MEDDEV 2.7/1, Rev.4.

Conformity Assessment Route: Annex: II of MDD/93/42/EEC on Medical Devices as amended .

Device Classification: Myval™ OCTACOR- Transcatheter Heart Valve is a surgically invasive long term use and implantable device used in direct contact with heart and incorporates animal tissue derivative, hence it is classified as "Class III" medical device as per Annexure IX, Rule 8 and Rule 17 of MDD/93/42/EEC, 14th June 1993 as amended by 2007/47/EC.

Certificate No.: EC Certificate No.: 1434-MDD-160/2021
EC Design certificate No.: 1434-MDD-159/2021

Certificate Issue Date: 2021-04-01

Certificate Valid till: 2024-04-08

European Authorized Representative: Obelis s.a.,
Bd. General Wahis 53,1030 Brussels, Belgium
Tel: +32. 2. 732. 59. 54
Fax: +32. 2. 732. 60. 03
E-mail: mail@obelis.net

Notifying Body: Polskie Centrum Badań i Certyfikacji S.A. z siedzibą w Warszawie
(Polish Center for Testing and Certification, PCBC) ul. Puławska 469, 02-844 Warszawa, Poland Website: www.pcbc.gov.pl
Phone: +48 22 46 45 200
Fax: +48 22 46 45 251

Notifying Body No.: 1434

Signature:

MERIL LIFE SCIENCES (P) LTD. VAPI

Name: Mr. Narendra Patel
Designation: Head – QA and RA
Date/Location: **Date**: 24.06.2022 **Location**: Vapi, Gujarat, INDIA

CE 1434

CERTIFICATE

EC Certificate No. 1434-MDD-159/2021

EC Design-examination
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the documentation submitted by:

Meril Life Sciences Pvt. Ltd.

Muktanand Marg, Chala, Vapi-396191
Gujarat, India

related to the medical device, class III

Transcatheter Heart Valve System

Brand names: Myval™-Transcatheter Heart Valve System, Myval™INCEPTION-Transcatheter Heart Valve System,Myval™ Neo Transcatheter Heart Valve System, Myval™ Pro Transcatheter Heart Valve System, Eternis™ Transcatheter Heart Valve System, Merineum™ Transcatheter Heart Valve System, Mavis™ Transcatheter Heart Valve System

The list of medical devices covered by this certificate is provided in the annex

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 2021-04-01 to 2024-04-08

The date of issue of the Certificate: 2021-04-01

The date of the first issue of the Certificate: 2019-04-09

CE 1434

Issued under the Contract No. **MD-11/2018**
Application No: 088/2021
Certificate bears the qualified signature.
Warsaw, 01/04/2021
Module H1

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.03.31 15:24:03 +02'00'
Vice-President

ANNEX TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-159/2021

List of medical devices covered by the certificate:

Transcatheter Heart Valve System includes the following components

1. **Transcatheter Heart Valve**
   Trade names: Myval™ , Myval™ INCEPTION, Myval™ Neo, Myval™ Pro, Eternis™, Merineum™, Mavis™
2. **Transcatheter Heart Valve Delivery System**
   Trade names: Navigator™, Navigator Neo™, Navigator Pro™, Navigator™ INCEPTION
3. **Balloon Dilatation Catheter**
   Trade names: Mammoth™, Mammoth Neo™
4. **Introducer Set**
   Trade names: Python™, Python™ Pro, Python™ INCEPTION
5. **Transcatheter Heart Valve Crimping Tool**
   Trade names: Val-De-Crimp™, Crocodial Compass™
   or
6. **Transcatheter Heart Valve Crimping Tool (Non-sterile)**
   Trade name: CrocoDial™

Models/Variants:

Transcatheter Heart Valve

Reference/Catalog Number							
Size (mm)	Myval™	Myval™ INCEPTION	Myval™ Neo	Myval™ Pro	Eternis™	Merineum™	Mavis™
Model-1							
20	MVL200	MVLI200	MVN200	MVLPR200	ETRNS200	MERNM200	MVS200
21.5	MVL215	MVLI215	MVN215	MVLPR215	ETRNS215	MERNM215	MVS215
23	MVL230	MVLI230	MVN230	MVLPR230	ETRNS230	MERNM230	MVS230
24.5	MVL245	MVLI245	MVN245	MVLPR245	ETRNS245	MERNM245	MVS245
26	MVL260	MVLI260	MVN260	MVLPR260	ETRNS260	MERNM260	MVS260
27.5	MVL275	MVLI275	MVN275	MVLPR275	ETRNS275	MERNM275	MVS275
29	MVL290	MVLI290	MVN290	MVLPR290	ETRNS290	MERNM290	MVS290
30.5	MVL305	MVLI305	MVN305	MVLPR305	ETRNS305	MERNM305	MVS305
32	MVL320	MVLI320	MVN320	MVLPR320	ETRNS320	MERNM320	MVS320
Model-1.1							
20	MVL1200	MVLI1200	MVN1200	MVLPR1200	ETRNS1200	MERNM1200	MVS1200
21.5	MVL1215	MVLI1215	MVN1215	MVLPR1215	ETRNS1215	MERNM1215	MVS1215
23	MVL1230	MVLI1230	MVN1230	MVLPR1230	ETRNS1230	MERNM1230	MVS1230
24.5	MVL1245	MVLI1245	MVN1245	MVLPR1245	ETRNS1245	MERNM1245	MVS1245
26	MVL1260	MVLI1260	MVN1260	MVLPR1260	ETRNS1260	MERNM1260	MVS1260
27.5	MVL1275	MVLI1275	MVN1275	MVLPR1275	ETRNS1275	MERNM1275	MVS1275
29	MVL1290	MVLI1290	MVN1290	MVLPR1290	ETRNS1290	MERNM1290	MVS1290
30.5	MVL1305	MVLI1305	MVN1305	MVLPR1305	ETRNS1305	MERNM1305	MVS1305
32	MVL1320	MVLI1320	MVN1320	MVLPR1320	ETRNS1320	MERNM1320	MVS1320
Model-2							
20	MVL2200	MVLI2200	MVN2200	MVLPR2200	ETRNS2200	MERNM2200	MVS2200
21,5	MVL2215	MVLI2215	MVN2215	MVLPR2215	ETRNS2215	MERNM2215	MVS2215
23	MVL2230	MVLI2230	MVN2230	MVLPR2230	ETRNS2230	MERNM2230	MVS2230
24,5	MVL2245	MVLI2245	MVN2245	MVLPR2245	ETRNS2245	MERNM2245	MVS2245
26	MVL2260	MVLI2260	MVN2260	MVLPR2260	ETRNS2260	MERNM2260	MVS2260
27,5	MVL2275	MVLI2275	MVN2275	MVLPR2275	ETRNS2275	MERNM2275	MVS2275
29	MVL2290	MVLI2290	MVN2290	MVLPR2290	ETRNS2290	MERNM2290	MVS2290
30,5	MVL2305	MVLI2305	MVN2305	MVLPR2305	ETRNS2305	MERNM2305	MVS2305
32	MVL2320	MVLI2320	MVN2320	MVLPR2320	ETRNS2320	MERNM2320	MVS2320

Transcatheter Heart Valve Delivery System

Balloon Diameter (mm)	Balloon Length (mm)	Shaft Diameter (Fr)	Navigator™	Navigator Neo™	Navigator Pro™	Navigator™ INCEPTION
Model-1(3 Marker Bands and With Flex Indicator on Handle)						
20	30	14	NVT20030	NVTN20030	NVTP20030	NVTI20030
21.5			NVT21530	NVTN21530	NVTP21530	NVTI21530
23			NVT23030	NVTN23030	NVTP23030	NVTI23030
24.5			NVT24530	NVTN24530	NVTP24530	NVTI24530
26			NVT26030	NVTN26030	NVTP26030	NVTI26030
27.5			NVT27530	NVTN27530	NVTP27530	NVTI27530
29			NVT29030	NVTN29030	NVTP29030	NVTI29030
27.5	35		NVT27535	NVTN27535	NVTP27535	NVTI27535
29			NVT29035	NVTN29035	NVTP29035	NVTI29035
30.5			NVT30535	NVTN30535	NVTP30535	NVTI30535
32			NVT32035	NVTN32035	NVTP32035	NVTI32035
20	30	16	NVS20030	NVNS20030	NVPS20030	NVIS20030
21.5			NVS21530	NVNS21530	NVPS21530	NVIS21530
23			NVS23030	NVNS23030	NVPS23030	NVIS23030
24.5			NVS24530	NVNS24530	NVPS24530	NVIS24530
26			NVS26030	NVNS26030	NVPS26030	NVIS26030
27.5	35		NVS27535	NVNS27535	NVPS27535	NVIS27535
29			NVS29035	NVNS29035	NVPS29035	NVIS29035
30.5			NVS30535	NVNS30535	NVPS30535	NVIS30535
32			NVS32035	NVNS32035	NVPS32035	NVIS32035
Model-1.1 (3 Marker Bands and Without Flex Indicator on Handle)						
20	30	14	NVT120030	NVTN120030	NVTP120030	NVTI120030
21.5			NVT121530	NVTN121530	NVTP121530	NVTI121530
23			NVT123030	NVTN123030	NVTP123030	NVTI123030
24.5			NVT124530	NVTN124530	NVTP124530	NVTI124530
26			NVT126030	NVTN126030	NVTP126030	NVTI126030
27.5			NVT127530	NVTN127530	NVTP127530	NVTI127530
29			NVT129030	NVTN129030	NVTP129030	NVTI129030
27.5	35		NVT127535	NVTN127535	NVTP127535	NVTI127535
29			NVT129035	NVTN129035	NVTP129035	NVTI129035
30.5			NVT130535	NVTN130535	NVTP130535	NVTI130535
32			NVT132035	NVTN132035	NVTP132035	NVTI132035

20	30	16	NVS120030	NVNS120030	NVPS120030	NVIS120030
21.5			NVS121530	NVNS121530	NVPS121530	NVIS121530
23			NVS123030	NVNS123030	NVPS123030	NVIS123030
24.5			NVS124530	NVNS124530	NVPS124530	NVIS124530
26			NVS126030	NVNS126030	NVPS126030	NVIS126030
27.5	35		NVS127535	NVNS127535	NVPS127535	NVIS127535
29			NVS129035	NVNS129035	NVPS129035	NVIS129035
30.5			NVS130535	NVNS130535	NVPS130535	NVIS130535
32			NVS132035	NVNS132035	NVPS132035	NVIS132035
Model-2 (4 Marker Bands and Without Flex Indicator on Handle)						
20	30	14	NVT220030	NVTN220030	NVTP220030	NVTI220030
21.5			NVT221530	NVTN221530	NVTP221530	NVTI221530
23			NVT223030	NVTN223030	NVTP223030	NVTI223030
24.5			NVT224530	NVTN224530	NVTP224530	NVTI224530
26			NVT226030	NVTN226030	NVTP226030	NVTI226030
27.5			NVT227530	NVTN227530	NVTP227530	NVTI227530
29			NVT229030	NVTN229030	NVTP229030	NVTI229030
27.5	35		NVT227535	NVTN227535	NVTP227535	NVTI227535
29			NVT229035	NVTN229035	NVTP229035	NVTI229035
30.5			NVT230535	NVTN230535	NVTP230535	NVTI230535
32			NVT232035	NVTN232035	NVTP232035	NVTI232035
20	30	16	NVS220030	NVNS220030	NVPS220030	NVIS220030
21.5			NVS221530	NVNS221530	NVPS221530	NVIS221530
23			NVS223030	NVNS223030	NVPS223030	NVIS223030
24.5			NVS224530	NVNS224530	NVPS224530	NVIS224530
26			NVS226030	NVNS226030	NVPS226030	NVIS226030
27.5	35		NVS227535	NVNS227535	NVPS227535	NVIS227535
29			NVS229035	NVNS229035	NVPS229035	NVIS229035
30.5			NVS230535	NVNS230535	NVPS230535	NVIS230535
32			NVS232035	NVNS232035	NVPS232035	NVIS232035

Balloon Dilatation Catheter

Balloon Diameter (mm)	Mammoth™	Mammoth Neo™
14	MTV1440	MTVN1440
16	MTV1640	MTVN1640
18	MTV1840	MTVN1840
20	MTV2040	MTVN2040
23	MTV2340	MTVN2340
25	MTV2540	MTVN2540
28	MTV2840	MTVN2840
30	MTV3040	MTVN3040

Introducer Set

Seth Size (Fr)	Reference/Catalog Number		
14	Python™	Python™ Pro	Python™ INCEPTION
	PHT14	PHTPR14	PHTI14

Transcatheter Heart Valve Crimping Tool (Sterile)

Reference/Catalog Number	
Val-de-Crimp™	CrocoDial Compass™
VLDC	CCDC

Transcatheter Heart Valve Crimping Tool (Non-sterile)

Reference/Catalog Number
CrocoDial™
CCD

Stopper Size	Transcatheter Heart Valve Size
Stopper 8	Primary Crimping of all Transcatheter Heart Valve Sizes
Stopper 3.5	20mm & 21.5mm
Stopper 4.0	23mm, 24.5mm, 26mm & 27.5mm
Stopper 4.5	29mm, 30.5mm & 32mm

CE 1434

Issued under the Contract No. **MD-11/2018**
Application No: 088/2021
Certificate bears the qualified signature.
Warsaw, 01/04/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.04.06 15:50:41 +02'00'

Vice-President

POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

KW/MC/2023/0066

Warsaw, 2023-03-28

Mr. Narendra Patel
Meril Life Sciences Pvt. Ltd.
Muktanand Marg, Chala
Vapi-396191, Gujarat, India

Dear Mr. Narendra Patel,

Polskie Centrum Badań i Certyfikacji S.A. declares that information contained in the EC Certificates No. 1434-MDD-160/2021 and 1434-MDD-159/2021 issued for Meril Life Sciences Pvt. Ltd., covering class III medical device "Transcatheter Heart Valve System", has been updated in the scope of the notified changes, registration number 024/2022/Z and 113/2022/Z.

The list of medical devices covered by the certificate 1434-MDD-159/2021 is provided below.

1. Transcatheter Heart Valve

Reference/Catalog Number									
Size (mm)	Myval™	Myval™ INCEPTION	Myval™ Neo	Myval™ Pro	Eternis™	Merineum™	Mavis™	Octacor	Myval™ OCTACOR
Model-1									
20	MVL200	MVLI200	MVN200	MVLPR200	ETRNS200	MERNM200	MVS200	OCTA200	MOCTA200
21.5	MVL215	MVLI215	MVN215	MVLPR215	ETRNS215	MERNM215	MVS215	OCTA215	MOCTA215
23	MVL230	MVLI230	MVN230	MVLPR230	ETRNS230	MERNM230	MVS230	OCTA230	MOCTA230
24.5	MVL245	MVLI245	MVN245	MVLPR245	ETRNS245	MERNM245	MVS245	OCTA245	MOCTA245
26	MVL260	MVLI260	MVN260	MVLPR260	ETRNS260	MERNM260	MVS260	OCTA260	MOCTA260
27.5	MVL275	MVLI275	MVN275	MVLPR275	ETRNS275	MERNM275	MVS275	OCTA275	MOCTA275

29	MVL290	MVLI290	MVN290	MVLPR290	ETRNS290	MERNM290	MVS290	OCTA290	MOCTA290
30.5	MVL305	MVLI305	MVN305	MVLPR305	ETRNS305	MERNM305	MVS305	OCTA305	MOCTA305
32	MVL320	MVLI320	MVN320	MVLPR320	ETRNS320	MERNM320	MVS320	OCTA320	MOCTA320
Model-1.1									
20	MVL1200	MVLI1200	MVN1200	MVLPR1200	ETRNS1200	MERNM1200	MVS1200	OCTA1200	MOCTA1200
21.5	MVL1215	MVLI1215	MVN1215	MVLPR1215	ETRNS1215	MERNM1215	MVS1215	OCTA1215	MOCTA1215
23	MVL1230	MVLI1230	MVN1230	MVLPR1230	ETRNS1230	MERNM1230	MVS1230	OCTA1230	MOCTA1230
24.5	MVL1245	MVLI1245	MVN1245	MVLPR1245	ETRNS1245	MERNM1245	MVS1245	OCTA1245	MOCTA1245
26	MVL1260	MVLI1260	MVN1260	MVLPR1260	ETRNS1260	MERNM1260	MVS1260	OCTA1260	MOCTA1260
27.5	MVL1275	MVLI1275	MVN1275	MVLPR1275	ETRNS1275	MERNM1275	MVS1275	OCTA1275	MOCTA1275
29	MVL1290	MVLI1290	MVN1290	MVLPR1290	ETRNS1290	MERNM1290	MVS1290	OCTA1290	MOCTA1290
30.5	MVL1305	MVLI1305	MVN1305	MVLPR1305	ETRNS1305	MERNM1305	MVS1305	OCTA1305	MOCTA1305
32	MVL1320	MVLI1320	MVN1320	MVLPR1320	ETRNS1320	MERNM1320	MVS1320	OCTA1320	MOCTA1320
Model-2									
20	MVL2200	MVLI2200	MVN2200	MVLPR2200	ETRNS2200	MERNM2200	MVS2200	OCTA2200	MOCTA2200
21.5	MVL2215	MVLI2215	MVN2215	MVLPR2215	ETRNS2215	MERNM2215	MVS2215	OCTA2215	MOCTA2215
23	MVL2230	MVLI2230	MVN2230	MVLPR2230	ETRNS2230	MERNM2230	MVS2230	OCTA2230	MOCTA2230
24.5	MVL2245	MVLI2245	MVN2245	MVLPR2245	ETRNS2245	MERNM2245	MVS2245	OCTA2245	MOCTA2245
26	MVL2260	MVLI2260	MVN2260	MVLPR2260	ETRNS2260	MERNM2260	MVS2260	OCTA2260	MOCTA2260
27.5	MVL2275	MVLI2275	MVN2275	MVLPR2275	ETRNS2275	MERNM2275	MVS2275	OCTA2275	MOCTA2275
29	MVL2290	MVLI2290	MVN2290	MVLPR2290	ETRNS2290	MERNM2290	MVS2290	OCTA2290	MOCTA2290
30.5	MVL2305	MVLI2305	MVN2305	MVLPR2305	ETRNS2305	MERNM2305	MVS2305	OCTA2305	MOCTA2305
32	MVL2320	MVLI2320	MVN2320	MVLPR2320	ETRNS2320	MERNM2320	MVS2320	OCTA2320	MOCTA2320

2. Transcatheter Heart Valve Delivery System

Balloon Diameter (mm)	Balloon Length (mm)	Shaft Diameter (Fr)	Navigator™	Navigator Neo™	Navigator Pro™	Navigator™ INCEPTION	Navigator™ Rondevu
Model-1 (3 Marker bands with pull wire & flex indicator on handle)							
20	30	14	NVT20030	NVTN20030	NVTP20030	NVTI20030	NVTR20030
21.5			NVT21530	NVTN21530	NVTP21530	NVTI21530	NVTR21530
23			NVT23030	NVTN23030	NVTP23030	NVTI23030	NVTR23030
24.5			NVT24530	NVTN24530	NVTP24530	NVTI24530	NVTR24530
26			NVT26030	NVTN26030	NVTP26030	NVTI26030	NVTR26030
27.5			NVT27530	NVTN27530	NVTP27530	NVTI27530	NVTR27530
29			NVT29030	NVTN29030	NVTP29030	NVTI29030	NVTR29030
27.5	35	14	NVT27535	NVTN27535	NVTP27535	NVTI27535	NVTR27535
29			NVT29035	NVTN29035	NVTP29035	NVTI29035	NVTR29035
30.5			NVT30535	NVTN30535	NVTP30535	NVTI30535	NVTR30535
32			NVT32035	NVTN32035	NVTP32035	NVTI32035	NVTR32035
20	30	16	NVS20030	NVNS20030	NVPS20030	NVIS20030	NVRS20030
21.5			NVS21530	NVNS21530	NVPS21530	NVIS21530	NVRS21530
23			NVS23030	NVNS23030	NVPS23030	NVIS23030	NVRS23030
24.5			NVS24530	NVNS24530	NVPS24530	NVIS24530	NVRS24530
26			NVS26030	NVNS26030	NVPS26030	NVIS26030	NVRS26030
27.5	35		NVS27535	NVNS27535	NVPS27535	NVIS27535	NVRS27535
29			NVS29035	NVNS29035	NVPS29035	NVIS29035	NVRS29035
30.5			NVS30535	NVNS30535	NVPS30535	NVIS30535	NVRS30535
32			NVS32035	NVNS32035	NVPS32035	NVIS32035	NVRS32035
Model-1.1 (3 Marker bands with pull wire & without flex indicator on handle)							
20	30	14	NVT120030	NVTN120030	NVTP120030	NVTI120030	NVTR120030

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Balloon Diameter (mm)	Balloon Length (mm)	Shaft Diameter (Fr)	Navigator™	Navigator Neo™	Navigator Pro™	Navigator™ INCEPTION	Navigator™ Rondevu
21.5			NVT121530	NVTN121530	NVTP121530	NVTI121530	NVTR121530
23			NVT123030	NVTN123030	NVTP123030	NVTI123030	NVTR123030
24.5			NVT124530	NVTN124530	NVTP124530	NVTI124530	NVTR124530
26			NVT126030	NVTN126030	NVTP126030	NVTI126030	NVTR126030
27.5			NVT127530	NVTN127530	NVTP127530	NVTI127530	NVTR127530
29			NVT129030	NVTN129030	NVTP129030	NVTI129030	NVTR129030
27.5	35	14	NVT127535	NVTN127535	NVTP127535	NVTI127535	NVTR127535
29			NVT129035	NVTN129035	NVTP129035	NVTI129035	NVTR129035
30.5			NVT130535	NVTN130535	NVTP130535	NVTI130535	NVTR130535
32			NVT132035	NVTN132035	NVTP132035	NVTI132035	NVTR132035
20	30	16	NVS120030	NVNS120030	NVPS120030	NVIS120030	NVRS120030
21.5			NVS121530	NVNS121530	NVPS121530	NVIS121530	NVRS121530
23			NVS123030	NVNS123030	NVPS123030	NVIS123030	NVRS123030
24.5			NVS124530	NVNS124530	NVPS124530	NVIS124530	NVRS124530
26			NVS126030	NVNS126030	NVPS126030	NVIS126030	NVRS126030
27.5	35		NVS127535	NVNS127535	NVPS127535	NVIS127535	NVRS127535
29			NVS129035	NVNS129035	NVPS129035	NVIS129035	NVRS129035
30.5			NVS130535	NVNS130535	NVPS130535	NVIS130535	NVRS130535
32			NVS132035	NVNS132035	NVPS132035	NVIS132035	NVRS132035
Model-2 (4 Marker bands with pull wire & without flex indicator on Handle)							
20			NVT220030	NVTN220030	NVTP220030	NVTI220030	NVTR220030
21.5			NVT221530	NVTN221530	NVTP221530	NVTI221530	NVTR221530
23			NVT223030	NVTN223030	NVTP223030	NVTI223030	NVTR223030
24.5			NVT224530	NVTN224530	NVTP224530	NVTI224530	NVTR224530

Balloon Diameter (mm)	Balloon Length (mm)	Shaft Diameter (Fr)	Navigator™	Navigator Neo™	Navigator Pro™	Navigator™ INCEPTION	Navigator™ Rondevu
26			NVT226030	NVTN226030	NVTP226030	NVTI226030	NVTR226030
27.5			NVT227530	NVTN227530	NVTP227530	NVTI227530	NVTR227530
29			NVT229030	NVTN229030	NVTP229030	NVTI229030	NVTR229030
27.5	35	14	NVT227535	NVTN227535	NVTP227535	NVTI227535	NVTR227535
29			NVT229035	NVTN229035	NVTP229035	NVTI229035	NVTR229035
30.5			NVT230535	NVTN230535	NVTP230535	NVTI230535	NVTR230535
32			NVT232035	NVTN232035	NVTP232035	NVTI232035	NVTR232035
20	30	16	NVS220030	NVNS220030	NVPS220030	NVIS220030	NVRS220030
21.5			NVS221530	NVNS221530	NVPS221530	NVIS221530	NVRS221530
23			NVS223030	NVNS223030	NVPS223030	NVIS223030	NVRS223030
24.5			NVS224530	NVNS224530	NVPS224530	NVIS224530	NVRS224530
26			NVS226030	NVNS226030	NVPS226030	NVIS226030	NVRS226030
27.5	35		NVS227535	NVNS227535	NVPS227535	NVIS227535	NVRS227535
29			NVS229035	NVNS229035	NVPS229035	NVIS229035	NVRS229035
30.5			NVS230535	NVNS230535	NVPS230535	NVIS230535	NVRS230535
32			NVS232035	NVNS232035	NVPS232035	NVIS232035	NVRS232035
Model-3 (4 Marker Bands, without pull wire & without flex indicator on handle)							
20	30	14	NVT320030	NVTN320030	NVTP320030	NVTI320030	NVTR320030
21.5			NVT321530	NVTN321530	NVTP321530	NVTI321530	NVTR321530
23			NVT323030	NVTN323030	NVTP323030	NVTI323030	NVTR323030
24.5			NVT324530	NVTN324530	NVTP324530	NVTI324530	NVTR324530
26			NVT326030	NVTN326030	NVTP326030	NVTI326030	NVTR326030
27.5			NVT327530	NVTN327530	NVTP327530	NVTI327530	NVTR327530
29			NVT329030	NVTN329030	NVTP329030	NVTI329030	NVTR329030

Balloon Diameter (mm)	Balloon Length (mm)	Shaft Diameter (Fr)	Navigator™	Navigator Neo™	Navigator Pro™	Navigator™ INCEPTION	Navigator™ Rondevu
27.5	35	14	NVT327535	NVTN327535	NVTP327535	NVTI327535	NVTR327535
29			NVT329035	NVTN329035	NVTP329035	NVTI329035	NVTR329035
30.5			NVT330535	NVTN330535	NVTP330535	NVTI330535	NVTR330535
32			NVT332035	NVTN332035	NVTP332035	NVTI332035	NVTR332035
20	30	16	NVS320030	NVNS320030	NVPS320030	NVIS320030	NVRS320030
21.5			NVS321530	NVNS321530	NVPS321530	NVIS321530	NVRS321530
23			NVS323030	NVNS323030	NVPS323030	NVIS323030	NVRS323030
24.5			NVS324530	NVNS324530	NVPS324530	NVIS324530	NVRS324530
26			NVS326030	NVNS326030	NVPS326030	NVIS326030	NVRS326030
27.5	35		NVS327535	NVNS327535	NVPS327535	NVIS327535	NVRS327535
29			NVS329035	NVNS329035	NVPS329035	NVIS329035	NVRS329035
30.5			NVS330535	NVNS330535	NVPS330535	NVIS330535	NVRS330535
32			NVS332035	NVNS332035	NVPS332035	NVIS332035	NVRS332035

3. Balloon Dilatation Catheter

Balloon Size (Diameter in mm)	Mammoth™	Mammoth Neo™
	Reference / Catalog Number	
14	MTV1440	MTVN1440
16	MTV1640	MTVN1640
18	MTV1840	MTVN1840
20	MTV2040	MTVN2040
23	MTV2340	MTVN2340
25	MTV2540	MTVN2540
28	MTV2840	MTVN2840

Balloon Size (Diameter in mm)	Mammoth™	Mammoth Neo™
	Reference / Catalog Number	
30	MTV3040	MTVN3040

4. Introducer Set

Sheath Size (Fr)	Python™	Python™ Pro	Python™ Inception	Python™ Novela
Model 1				
14	PHT14	PHTPR14	PHTI14	PHTNV14
Model 2				
14	PTH14	PTHPR14	PTHI14	PTHNV14

5. Transcatheter Heart Valve Crimping Tool

Model 1 (Sliding Mechanism)	
Val-de-Crimp™	CrocoDial Compass™
VLDC	CCDC
Model 2 (Geared Mechanism)	
VLDC2	CCDC2

Implementation of the change does not represent a significant change in design or intended purpose under MDR 2017/745 Article 120(3) and that certificates 1434-MDD-160/2021 and 1434-MDD-159/2021 issued for Meril Life Sciences Pvt. Ltd. on 2021-04-01 remain valid until 2024-04-08.

Sincelery

Tomasz Koeber

Elektronicznie podpisany przez Tomasz Artur Koeber
Data: 2023.03.28 14:27:58 +02'00'

Head of Medical Devices Certification Department

Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Meril Life Science Pvt. Ltd.
Manufacturer address and contact details	Meril Life Sciences Pvt. Ltd, Muktanand Marg, Chala, Vapi-396191, Gujarat Contact: +91(260) 2408000;
Single Registration Number (SRN) (if available)	IN-MF-000008308

Authorised Representative name (if applicable)	Obelis s.a.
Authorised Representative address and contact details	Obelis s.a., Bld. General Wahis 53, 1030 Brussels, Belgium. Tel: +32. 2. 732. 59. 54 Fax: +32. 2. 732. 60. 03 E-mail: mail@obelis.net
Single Registration Number (SRN) (if available)	BE-AR-000000106

Notified body name (if applicable)	☑See attached schedule
Notified body number (if applicable)	☑See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☑See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☑See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

End date of extended validity/transition period	☑See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

  ☑ Expired/expires *after* 20 March 2023:

  Choose one applicable statement:

  ☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Unclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024; therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☑ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name:
Meril Life Science Pvt Ltd

Location & Date:
Vapi;
Signature, Print Name, Title

NARENDRA BABUBHAI PATEL

Digitally signed by NARENDRA BABUBHAI PATEL
Date: 2024.02.28 15:42:43 +05'30'

Narendra Patel
General Manager – QA and RA

Contact Details (at least email)
narendra.patel@merillife.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / ttransition period**	**Substitute Device(s)** (if applicable)
Transcatheter Heart Valve System **i. Generic name:** Transcatheter Heart Valve System **ii. Brand names:** Myval™ Myval™ INCEPTION Myval™ Neo Myval™ Pro Eternis™ Merineum™ Mavis™ Octacor™ Myval™ OCTACOR Myval™ OCTAPRO **Components of the System:** **i. Generic name:** Transcatheter Heart Valve **ii.Brand names**: Myval™ Myval™ INCEPTION Myval™ Neo Myval™ Pro Eternis™	EC Certificate No. 1434 MDD-160/2021 EC Design Certificate No. 1434-MDD159/2021	08th April 2024	Polish Centre for Testing and Certification	Polish Centre for Testing and Certification	31 December 2027	Yes **Transcatheter Heart Valve System** **i. Generic name:** Transcatheter Heart Valve System **ii. Brand name:** Myval™ Genesis Myval™ Integra

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Merineum™ Mavis™ Octacor™ Myval™ OCTACOR Myval™ OCTAPRO **iii. Generic name:** **Transcatheter Heart Valve Delivery System** **iv. Brand name:** Navigator™ Navigator Neo™ Navigator Pro™ Navigator™ Inception Navigator™ RONDEVU **v. Generic name:-Balloon Dilatation Catheter** **vi. Brand name:** Mammoth™ Mammoth Neo™ **vii. Generic name:** **Introducer Set** **viii. Brand name:** Python™ Python™ Pro Python™ Inception Python™ Novela **viii. Generic name:** Transcatheter Heart Valve Crimping Tool (Sterile) **ix. Brand name:** Val-De-Crimp™ Crocodial Compass or **x. Generic name:** Transcatheter Heart Valve Crimping Tool (Non-sterile)						

xi. Brand name: CrocoDial™ **Basic UDI-DI for Transcatheter Heart Valve System:** 89042249THVSWZ						
Pericardial Bioprosthesis **i. Generic name:** Pericardial Bioprosthesis **ii. Brand name:** Dafodil™ Dafodil Neo™ Flomero™ Freesia™ **Basic UDI-DI for Pericardial Bioprosthesis:** 89042249PBE8	EC Certificate No.1434-MDD-352/2020 EC Design Certificate No.1434-MDD-351/2020	27th May 2024	Polish Centre for Testing and Certification	Polish Centre for Testing and Certification	31 December 2027	NA

NARENDRA BABUBHAI PATEL

Digitally signed by NARENDRA BABUBHAI PATEL
Date: 2024.02.28 15:43:05 +05'30'

Narendra Patel
General Manager – QA and RA

POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

KW/MC/2024/0067

Warsaw, 2024.02.26

Meril Life Sciences Pvt. Ltd,
Muktanand Marg, Chala,
Vapi-396191, Gujarat
Contact: +91(260) 2408000;
SRN Number: IN-MF-000008308

Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Polish Centre for Testing and Certification, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1434 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Meril Life Sciences Pvt. Ltd,
Muktanand Marg, Chala,
Vapi-396191, Gujarat
Contact: +91(260) 2408000;
SRN Number: IN-MF-000008308

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

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Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

☐26 May 2026 for Class III custom-made implantable devices
☑31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
☐31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
☐31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Tomasz Koeber

Elektronicznie podpisany
przez Tomasz Artur Koeber
Data: 2024.02.26 14:42:30
+01'00'

Tomasz Koeber

Head of Medical Device Certification Department

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device Name: Transcatheter Heart Valve System **Trade names:** Myval™ Genesis System, Myval™ Integra System **Components of the System:** i. Generic name: Transcatheter Heart Valve Brand names: Myval™ Genesis (1st brand) and Myval™ Integra (2nd brand) ii. Generic name: Transcatheter Heart Valve Delivery System Brand name: Navigator™, Navigator Neo and Navigator Pro™ iii. Generic name: Balloon Dilatation Catheter Brand name: Mammoth™, and Mammoth Neo™ iv. Generic name: Introducer Set Brand name: Python™, Python™ Pro, Python™ Inception and Python™ Novela v. Generic name: Transcatheter Heart Valve Crimping Tool Brand name: Val-De-Crimp™, Crocodial Compass™	Class III	**Generic name:** Transcatheter Heart Valve System **Brand names:** Myval™ , Myval™ INCEPTION , Myval™ Neo , Myval™ Pro, Eternis™, Merineum™,Mavis™, Octacor™, Myval™ OCTACOR and Myval™ OCTAPRO **Components of the System:** i. Generic name: Transcatheter Heart Valve Brand names: Myval™ , Myval™ INCEPTION , Myval™ Neo , Myval™ Pro , Eternis™ , Merineum™,Mavis™, Octacor™, Myval™ OCTACOR and Myval™ OCTAPRO ii. Generic name: Transcatheter Heart Valve Delivery System Brand name: Navigator™, Navigator Neo™ , Navigator Pro™ and Navigator™ Inception and Navigator™ RONDEVU iii. Generic name:——Balloon Dilatation Catheter Brand name: Mammoth™ and Mammoth Neo™	EC Certificate No. 1434 MDD-160/2021 EC Design Certificate No. 1434-MDD-159/2021

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
vi. Generic name: Confirmation Gauge **Basic UDI-DI:** 89042249THVSAWT		iv. Generic name: Introducer Set **Brand name:** Python™, Python™ Pro and Python™ Inception and Python™ Novela v. Generic name: Transcatheter Heart Valve Crimping Tool (Sterile) Brand name: Val-De-Crimp™ and Crocodial Compass Or vi. Generic name: Transcatheter Heart Valve Crimping Tool (Non-sterile) Brand name: CrocoDial™	
Device Name: Pericardial Bioprosthesis **Basic UDI-DI:** 89042249PBE8	Class III	N/A	EC Certificate No. 1434 MDD-352/2020 EC Design Certificate No.1434 MDD-351/2020

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
26.02.2024	KW/MC/2024/0067	Initial issue