Slovakia Medical

spoločne od roku 1994

Ministerstvo zdravotníctva SR
Odbor kategorizácie, cenotvorby a hodnotenia
zdravotníckych pomôcok a dietetických potravín
Limbová 2
837 52 Bratislava 37

V Bratislave, dňa 9.5.2023

Doplnenie informácií k žiadosti na základe Vašej výzvy č. S00090-2023-OKCHZPDP-12646

Na základe Vašej výzvy č. S00090-2023-OKCHZPDP-12646 zo dňa 4.5.2023 dopĺňame k žiadosti o zaradenie zdravotníckej pomôcky P4335A, Katéter PTA balónikový dilatačný JADE; pre vodič 0.018", rôzne veľkosti rozmery do zoznamu kategorizovaných špeciálnych zdravotníckych materiálov nasledovné informácie:

- **podľa § 45 ods. 4 písmeno a) doplniť aktuálne platný certifikát CE;**

Radi by sme pripomenuli, že Nariadením Európskeho parlamentu a Rady (EÚ) č. 2023/607 sa za určitých podmienok predĺžila platnosť certifikátov CE osvedčujúcich posúdenie zhody podľa smernice MDD do 31. 12. 2028 pre zdravotnícke pomôcky triedy IIa. Prikladáme prehlásenie výrobcu, ktoré vyhlasuje splnenie príslušných podmienok, a tým oprávňuje na uplatnenie príslušných prechodných ustanovení čl. 120 MDR.

- **vysvetliť rozdiel adresy medzi výrobcami zdravotníckej pomôcky uvedenými na stránke ŠÚKL a v žiadosti;**

Prikladáme vyhlásenie výrobcu, ktoré vysvetľuje vzťah medzi jednotlivými subjektmi - členmi holdingu OrbusNeich Medical. Ide o dcérske spoločnosti toho istého vlastníka, pričom väčšina výrobkov sa vyrába pod označením výrobcu OrbusNeich Medical (Shenzhen) aj OrbusNeich Medical B.V.

Za kladné spracovanie vopred ďakujem.

S úctou,

SLOVAKIA MEDICAL, s.r.o.
Bárdošova 2, 831 01 Bratislava
IČO: 31 385 265
IČ DPH: SK2020304154

Ing. Filip Jakubec
SLOVAKIA MEDICAL, s.r.o.

OrbusNeich®
Pioneers in life-changing technologies

23 March 2023

Declaration Letter

To whom it may concern,

On 20 March 2023, the Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices was published in the Official Journal of the European Union (OJEU) with immediate effect.

The new amending Regulation extends the MDR transition timelines while also recognizing as valid previously issued MDD, AIMDD Certificates for the duration of those longer transition timelines. This allows manufacturers to continue placing their devices on the market based on compliance to the Directives while they continue the transition of their devices to the MDR.

The table below shows the new transition timelines that apply for different categories of devices subject to the manufacturer submitting an MDR application by the 26 May 2024 and having a signed formal written agreement with a Notified Body by the 26 Sep 2024.

Transition timelines	Devices
31 December 2027	Devices covered by valid MDD/AIMDD Certificates (as of 2023/03/20) and that are Class III, or Class IIb implantable devices excluding well-established technologies (WET) under MDR
31 December 2028	Devices covered by valid MDD/AIMDD Certificates (as of 2023/03/20) and that are Class IIb devices (excluding Class IIb implantable non-WET), or Class IIa devices, or Class I sterile devices or Class I devices with a measuring function

OrbusNeich hereby confirm the fulfilment of the conditions specified in the amending regulation. The longer transition timelines apply for following legacy devices:

OrbusNeich®
Pioneers in life-changing technologies

Legacy devices with Manufacturer as OrbusNeich Medical (Shenzhen) Co., Ltd

Certificate(s)/Devices	Certificate Number	Certificate Expiry Date	Transition Timeline
EC Certificate -Full Quality Assurance System	CE 619984	20 Apr 2023	31 December 2028
Sapphire NC 24 Coronary Dilatation Catheter	CE 706141	26 May 2024	31 December 2027
Sapphire 3 Coronary Dilatation Catheter	CE 712825	26 May 2024	31 December 2027
Sapphire II PRO Coronary Dilatation Catheter	CE 619994	26 May 2024	31 December 2027
Scoreflex NC Coronary Dilatation Catheter	CE 646778	26 May 2024	31 December 2027
Sapphire II NC Coronary Dilatation Catheter	CE 649483	19 Feb 2024	31 December 2027
Sapphire II (RX) Coronary Dilatation Catheter	CE649487	26 May 2023	31 December 2027
Teleport Microcatheter	CE 673072	05 Mar 2023	31 December 2027
JADE PTA Balloon Dilatation Catheter	N/A (Class IIa device; refer to CE 619984)		31 December 2028
Scoreflex PTA Balloon Dilatation Catheter	N/A (Class IIa device; refer to CE 619984		31 December 2028

Legacy devices with Manufacturer as OrbusNeich Medical B.V.

Certificate(s)/Devices	Certificate Number	Certificate Expiry Date	Transition Timeline
EC Certificate -Full Quality Assurance System	CE 619995	21 Apr 2023	31 December 2028
Sapphire NC 24 Coronary Dilatation Catheter	CE 706144	26 May 2024	31 December 2027
Sapphire 3 Coronary Dilatation Catheter	CE 712118	26 May 2024	31 December 2027
Sapphire II PRO Coronary	CE 620000	26 May 2024	31 December 2027

OrbusNeich®
Pioneers in life-changing technologies

Dilatation Catheter			
Scoreflex NC Coronary Dilatation Catheter	CE 646780	26 May 2024	31 December 2027
Combo Bio-Engineered Sirolimus Eluting Stent (Combo Stent)	CE 649477	23 May 2023	31 December 2027
Scoreflex Coronary Dilatation Catheter	CE 649479	26 May 2023	31 December 2027
Sapphire NC Coronary Dilatation Catheter	CE 649480	15 June 2023	31 December 2027
Sapphire II NC Coronary Dilatation Catheter	CE 649484	19 Feb 2024	31 December 2027
Sapphire II (RX) Coronary Dilatation Catheter	CE649488	26 May 2023	31 December 2027
COMBO Plus Dual Therapy Stent (COMBO Plus Stent)	CE 649589	26 May 2024	31 December 2027
Teleport Microcatheter	CE 673071	05 Mar 2023	31 December 2027
JADE PTA Balloon Dilatation Catheter	N/A (Class IIa device; refer to CE 619995)		31 December 2028
Scoreflex PTA Balloon Dilatation Catheter	N/A (Class IIa device; refer to CE 619995)		31 December 2028

Yours faithfully,

Jerry 2023/4/13

Jerry Cheung
Senior Director, Regulatory Affairs
OrbusNeich Medical Co., Ltd.

OrbusNeich®

Pioneers in life-changing technologies

May 4, 2023

TO WHOM IT MAY CONCERN

The statements below are provided to clarify the relationship between OrbusNeich Medical B.V. and OrbusNeich Medical (Shenzhen) Co., Ltd:

1. OrbusNeich Medical (Shenzhen) Co., Ltd and OrbusNeich Medical B.V the Legal Manufacturers.
2. OrbusNeich Medical (Shenzhen) Co., Ltd and OrbusNeich Medical B.V. are wholly owned subsidiary of OrbusNeich Medical Limited.
3. OrbusNeich Medical (Shenzhen) Co., Ltd and OrbusNeich B.V. as Legal Manufacturers are responsible for the design, manufacture, packaging and labelling of medical devices before they are placed on the market under OrbusNeich brand.
4. Sales, Marketing and Distribution activities are performed by Orbus International B.V. as an approved supplier in accordance with the requirements of the OrbusNeich Medical QMS.

For and on behalf of OrbusNeich Medical B.V:

ORBUSNEICH MEDICAL B.V. OFFICIAL DOCUMENT

Jantheo Dam _____ may 4 2023

Quality Assurance Manager

OrbusNeich Medical B.V.

Drs. W. van Royenstraat 5
3871 AN Hoevelaken
The Netherlands

Tel: +31.33.254.1150

info@orbusneich.com
www.OrbusNeich.com

ABN AMRO Bank Account Numbers
For Euro: NL82 ABNA 0443 290 636
For US$: NL87 ABNA 0545 831 768
SWIFT: ABNANL2A

Chamber of Commerce: 32116966
VAT Number: NL817323636B01