MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2024/31/01
CL1/V3

Esteemed

DOĞSAN TIBBİ MALZEME SANAYİ A.Ş.
Rize Cad. 91A, 61080, Ortahisar, Trabzon

Notified Body Confirmation Letter Reference: MDR 00115

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, Kiwa Cermet Italia, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0476 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:

DOĞSAN TIBBİ MALZEME SANAYİ A.Ş.
Rize Cad. 91A, 61080, Ortahisar, Trabzon
SRN Number: TR-MF-000016026

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.
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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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,
Dr.ssa Frabetti Alessia
Medical Device Division Manager

Alessia Frabetti

Firmato digitalmente da: ALESSIA FRABETTI
Data: 27/03/2024 13:04:41

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	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
-	-	-	-
-	-	-	-

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	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
PEGELAK® Poly(glycolide-co-lactide) Synthetic, Absorbable, Braided STERILE SURGICAL SUTURE **PEGELAK®rapid Poly(glycolide-co-lactide) Synthetic, Absorbable, Braided STERILE SURGICAL SUTURE**	Class III	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	1984-MDD-21-784; NB1984 1984-MDD-21-791; NB 1984
TEKMON® Poly(glycolide-co-caprolactone) Synthetic, Absorbable, Monofilament Sterile Surgical Suture	Class III	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	1984-MDD-21-784; NB1984 1984-MDD-21-795; NB1984
KANSTAT® Absorbable Hemostat (Oxidised Regenerated Cellulose)	Class III	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	1984-MDD-21-784; NB1984 1984-MDD-21-789; NB1984
İPEK(SILK) Non-Absorbable, Braided, Coated Sterile Surgical Suture	Class IIb implantable WET device	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	1984-MDD-21-784; NB1984 1984-MDD-21-788; NB1984
PEGESORB® Polyglycolic Acid Synthetic, Absorbable, Braided STERILE SURGICAL SUTURE **PEGESORB®rapid**	Class III	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	1984-MDD-21-784; NB1984 1984-MDD-21-792; NB 1984

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	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Polyglycolic Acid Synthetic, Absorbable, Braided STERILE SURGICAL SUTURE			
TEKTEL® Surgical Stainless Steel Wire Suture, U.S.P / E.P.	Class IIb implantable WET device	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	1984-MDD-21-784; NB1984
XNAT® -TEKMON Knotless Tissue Control Device Poly(glycolide-co-caprolactone) Synthetic Absorbable Monofilament Barbed Suture	Class III	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	1984-MDD-21-784; NB1984 1984-MDD-21-798; NB 1984
PEGELAK®C-plus Antibacterial Poly(glycolide-co-lactide) Absorbable, braided, sterile surgical suture	Class III	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	1783-MDD-058; NB1783 1783-MDD-057; NB 1783
DOPACE® TEMPORARY PACING WIRE (TPW)	Class III	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	1984-MDD-21-784; NB1984 1984-MDD-21-787; NB 1984
TROFILEN® Polyvinylidene fluoride Synthetic, Non-Absorbable, Monofilament Sterile Surgical Suture	Class IIb implantable WET device	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	1984-MDD-21-784; NB1984 1984-MDD-21-796; NB 1984
ONTREX® Polyethylene Synthetic Non absorbable Multifilament Sterile Surgical Suture and Tape	Class IIb implantable WET device	Identification of the corresponding device under MDD ☒ Same ☐ Substitute	1984-MDD-21-784; NB1984
DAYLON® Polyamide Synthetic, Non-Absorbable, Monofilament Sterile Surgical Suture	Class IIb implantable WET device	Identification of the corresponding device under MDD ☒ Same	1984-MDD-21-784; NB1984 1984-MDD-21-786; NB 1984

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	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
		☐ Substitute	

Confirmation Letter Revision History

Rev. *Rev.*	**Date** *Date*	**Action** *Azione*
00	2023/10/11	Initial issue: • PEGELAK® Poly(glycolide-co-lactide) Synthetic, Absorbable, Braided STERILE SURGICAL SUTURE PEGELAK®rapid Poly(glycolide-co-lactide) Synthetic, Absorbable, Braided STERILE SURGICAL SUTURE • TEKMON® Poly(glycolide-co-caprolactone) Synthetic, Absorbable, Monofilament Sterile Surgical Suture • KANSTAT® Absorbable Hemostat (Oxidised Regenerated Cellulose) • İPEK(SILK) Non-Absorbable, Braided, Coated Sterile Surgical Suture
01	2024/31/01	• İPEK(SILK) Non-Absorbable, Braided, Coated Sterile Surgical Suture (The classification of product has been updated)
02	2024/03/22	Extension products have been added, ref. CERBO0050924 and CERBO0148524. • PEGESORB® Polyglycolic Acid Synthetic, Absorbable, Braided STERILE SURGICAL SUTURE • PEGESORB®rapid Polyglycolic Acid Synthetic, Absorbable, Braided STERILE SURGICAL SUTURE • TEKTEL® Surgical Stainless Steel Wire Suture, U.S.P / E.P. • XNAT® -TEKMON Knotless Tissue Control Device Poly(glycolide co-caprolactone) Synthetic Absorbable Monofilament Barbed Suture • PEGELAK®C-plus Antibacterial Poly(glycolide co-lactide) Absorbable, braided, sterile surgical suture • DOPACE® TEMPORARY PACING WIRE (TPW) • TROFILEN® Polyvinylidene fluoride Synthetic, Non Absorbable, Monofilament Sterile Surgical Suture • ONTREX® Polyethylene Synthetic Non absorbable Multifilament Sterile Surgical Suture and Tape • DAYLON® Polyamide Synthetic, Non Absorbable, Monofilament Sterile Surgical Suture

For further information on the content of the letter or verification of the validity of the letter please contact medical@kiwa.com or phone at +39.051.4593.111