Kiwa Cermet Italia

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2024/02/19
CL1/V4

Esteemed

SMI AG
Steinerberg 8,
4780 St. Vith
Belgium

Notified Body Confirmation Letter Reference: CERBO0385122

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, NB Name, 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:

SMI AG
Steinerberg 8,
4780 St. Vith
Belgium

SRN Number: BE-MF-000017536

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 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withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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,
Dr.ssa Frabetti Alessia
Medical Device Division Manager

NB 0476

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
N/A	N/A	N/A	N/A

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
Sterile synthetic absorbable surgical suture (54040200215FL)	Class III	N/A	301011861AD 301011861DE4 EKAPTY, NB No. 0653
Sterile synthetic absorbable surgical suture (54040200211FC)	Class III	N/A	301011861AD 301011861DE5 301011861DE2 EKAPTY, NB No. 0653
Sterile synthetic absorbable surgical suture (54040200213FG)	Class III	N/A	301011861AD 301011861DE6 EKAPTY, NB No. 0653
Sterile synthetic absorbable surgical suture (54040200216FN)	Class III	N/A	301011861AD 301011861DE3 EKAPTY, NB No. 0653
Sterile non-absorbable surgical sutures (54040200205FH)	Class IIb excluding Class IIb implantable non-WET	N/A	301011861AD EKAPTY, NB No. 0653
Sterile non-absorbable surgical sutures (54040200207FM)	Class IIb excluding Class IIb implantable non-WET	N/A	301011861AD EKAPTY, NB No. 0653
Sterile non-absorbable surgical sutures (54040200208FP)	Class IIb excluding Class IIb implantable non-WET	N/A	301011861AD EKAPTY, NB No. 0653
Sterile non-absorbable surgical sutures (54040200209FR)	Class IIb excluding Class IIb implantable non-WET	N/A	301011861AD EKAPTY, NB No. 0653
STERILE SURGICAL BLADES DISPOSABLE SCALPELS (54040200224FM)	Class IIa	N/A	301011861AD EKAPTY, NB No. 0653

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/02/19	Rev.0	Initial issue

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

NB 0476