Kiwa Cermet Italia

MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 05/06/2023
CL1/V3

Esteemed **COSMED S.r.l.**
Via dei Piani di Monte Savello, 37 00041 Albano Laziale (Roma)

Notified Body Confirmation Letter Reference: MDR 00035

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:

COSMED S.r.l.
Via dei Piani di Monte Savello, 37 00041 Albano Laziale (Roma)

SRN Number (if available): /

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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

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
805240018mQSH	Class IIa	microQuark ☒ Same ☐ Substitute	Certificate MED 9811 NB# 0476
805240018QSpiroTK	Class IIa	Quark SPIRO Quark PFT1 ☒ Same ☐ Substitute	Certificate MED 9811 NB# 0476
805240018QPFTA2	Class IIa	Quark PFT Quark PFT2 Quark PFT3 Quark PFT4 Quark PFT2 ergo Quark PFT4 ergo ☒ Same ☐ Substitute	Certificate MED 9811 NB# 0476
805240018QCPET6D	Class IIa	Quark CPET Quark PFT ergo ☒ Same ☐ Substitute	Certificate MED 9811 NB# 0476
805240018QRMRAV	Class IIa	Quark RMR ☒ Same ☐ Substitute	Certificate MED 9811 NB# 0476
805240018QBoxD6	Class IIa	Q-Box ☒ Same ☐ Substitute	Certificate MED 9811 NB# 0476
805240018Qi2mCM	Class IIa	Q-i2m ☒ Same ☐ Substitute	Certificate MED 9811 NB# 0476
805240018K5N4	Class IIa	K5 ☒ Same ☐ Substitute	Certificate MED 9811 NB# 0476
805240018QNRGA2	Class IIa	Q-NRG Q-NRG+ ☒ Same ☐ Substitute	Certificate MED 9811 NB# 0476

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
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Confirmation Letter Revision History

Rev. *Rev.*	**Date** *Date*	**Action** *Azione*
00	05/06/2023	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