MEDICAL DEVICES DIVISION
Granarolo dell'Emilia (BO), 2024/03/21
CL1/V4

Esteemed

Speciality Fibres and Materials Limited
Galaxy House, 31 Herald Way, Binley Industrial Estate, Coventry, CV3 2RQ, United Kingdom

Notified Body Confirmation Letter Reference: CERBO0095824

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 Italy, 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:

Speciality Fibres and Materials Limited

Galaxy House, 31 Herald Way, Binley Industrial Estate, Coventry, CV3 2RQ, United Kingdom

SRN Number (if available): GB-MF-000004153

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

Alessia Frabetti

Firmato digitalmente da: ALESSIA FRABETTI
Data: 04/04/2024 13:49:03

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
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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
Silver Alginate (Antimicrobial Calcium Alginate with Silver wound dressing/packing rope)	Class III	Identification of the corresponding device under MDD ✓ Same □ Substitute	1984-MDD-21-754 Silver Alginate NB: 1984
Venus Ag (Wound Dressing with Antimicrobial Silver and Strengthening Cellulose Fibre)	Class III	Identification of the corresponding device under MDD ✓ Same □ Substitute	1984-MDD-21-769 Venus Ag NB: 1984
Pluto Ag (Antimicrobial Calcium Alginate with Silver Wound Dressing / Rope)	Class III	Identification of the corresponding device under MDD ✓ Same □ Substitute	1984-MDD-21-753 Pluto Ag NB: 1984

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/03/21	Rev.00	Initial issue: Silver Alginate (Antimicrobial Calcium Alginate with Silver wound dressing/packing rope), Venus Ag (Wound Dressing with Antimicrobial Silver and Strengthening Cellulose Fibre), Pluto Ag (Antimicrobial Calcium Alginate with Silver Wound Dressing / Rope)

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