Smith & Nephew Medical Limited
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Smith+Nephew

Manufacturer's Confirmation in regard to Regulation 2023/607

with respect to the certificates issued under Council Directive 93/42/EEC on medical devices ("MDD"), ("Directive Certificates") and their validity per Article 120(2) of Regulation (EU) 2017/745 on medical devices as amended by Regulation 2023/607 of 20 March 2023 ("MDR") and with respect to the Devices' and its Manufacturer's compliance with the conditions to continued placing on the market as per Article 120(3) of the MDR

Manufacturer name	Smith & Nephew Medical Ltd.
Manufacturer address	101 Hessle Road Hull HU3 2BN United Kingdom
Manufacturer EUDAMED SRN	GB-MF-000017580
Notified Body name	BSI
Notified Body number	2797

This is confirmation that the devices listed below meet following conditions for extension of certificates issued under Council Directive Council Directive 93/42/EEC on medical devices (MDD) as stated in Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 on medical devices

- The certificate(s) covering the listed devices was valid on the 26 May 2021.
- The device(s) continue to comply with Directive 93/42/EEC (MDD)
- There are no significant changes in the design and intended purpose since 26 May 2021.
- The device(s) do not present unacceptable risks to health or safety of patients, users or other persons, or to other aspects of the protection of public health
- A quality management system in accordance with Article 10(9), Regulation (EU) 2017/745 (MDR) has been put in place by the manufacturer no later than 26 May 2024.
- A formal application to the notified body in accordance with Section 4.3, first subparagraph, of Annex VII, Regulation (EU) 2017/745 (MDR) for conformity assessment has been made for the device(s) listed and a signed written agreement is in place in accordance with Section 4.3, second subparagraph, of Annex VII, Regulation (EU) 2017/745 (MDR). This was completed prior to the expiry of the certificate
- Post-market surveillance, market surveillance, vigilance, registration of economic operators in accordance with Regulation (EU) 2017/745 (MDR) is in place for the device(s) listed.

Signature: 

Date: 04/April/2023

Print name: Sam Greenhalgh

Title/position: Regulatory Affairs Director

Smith & Nephew Medical Ltd.

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Schedule of devices

Catalog Item	Description	Certificate number	Expiry date on the certificate	Extended expiry date
66800034	DURAFIBER AG 5X5CM CTN 10	CE 568730	20-Jun-22	31-Dec-27
66800035	DURAFIBER AG 10X10CM CTN 10	CE 568730	20-Jun-22	31-Dec-27
66800036	DURAFIBER AG 15X15CM CTN 5	CE 568730	20-Jun-22	31-Dec-27
66800037	DURAFIBER AG 20X30CM CTN 5	CE 568730	20-Jun-22	31-Dec-27
66800038	DURAFIBER AG 2X45CM CTN 5	CE 568730	20-Jun-22	31-Dec-27
66800578	DURAFIBER AG 5X5CM CTN 10	CE 568730	20-Jun-22	31-Dec-27
66800579	DURAFIBER AG 10X10CM CTN 10	CE 568730	20-Jun-22	31-Dec-27
66800580	DURAFIBER AG 15X15CM CTN5	CE 568730	20-Jun-22	31-Dec-27
66800581	DURAFIBER AG 20X30CM CTN 5	CE 568730	20-Jun-22	31-Dec-27
66800582	DURAFIBER AG 2X45CM CTN 5	CE 568730	20-Jun-22	31-Dec-27
66800583	DURAFIBER AG 4X10CM CTN 5	CE 568730	20-Jun-22	31-Dec-27
66800584	DURAFIBER AG 4X20CM CTN 5	CE 568730	20-Jun-22	31-Dec-27
66800585	DURAFIBER AG 4X30CM CTN 5	CE 568730	20-Jun-22	31-Dec-27