Extremity Medical LLC
300 Interpace Parkway, Building A, 2nd Floor,
Parsippany-Troy Hills NJ 07054
New Jersey, USA

Date: 26 September 2024

Confirmation Letter
Reference: US_018334_2024_02

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, HTCert, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2803 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:

Extremity Medical LLC
300 Interpace Parkway, Building A, 2nd Floor,
Parsippany-Troy Hills NJ 07054 New Jersey, USA
SRN: US-MF-000018334

Application ID: US_018334_24_05_02
Application Date: 24/05/2024
Contract for MDR certification signed on 23/09/2024

The devices covered by the formal application and the written agreement mentioned above are identified below. HTCert is also responsible for appropriate surveillance of the 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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,

Filippos Kottis
Certification Director

Devices covered by this letter

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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Omni Foot and Ankle Plating System	Class IIb	n/a	CE 542056 NB 2797
Intraossous Fixation System	Class IIb	n/a	CE 542056 NB 2797
Axis Charcot Fixation System	Class IIb	n/a	CE 542056 NB 2797
HammerFiX PEEK Hammertoe Implant System	Class IIb	n/a	CE 542056 NB 2797
AlignX Ankle Fusion System	Class IIb	n/a	CE 542056 NB 2797
Compress X 2	Class IIb	n/a	CE 542056 NB 2797
Curette	Class IIa	n/a	CE 542056 NB 2797
Distractor	Class IIa	n/a	CE 542056 NB 2797
Drills	Class IIa	n/a	CE 542056 NB 2797
Guide wire	Class IIa	n/a	CE 542056 NB 2797
Bone Reamer	Class IIa	n/a	CE 542056 NB 2797
Bone Rasp	Class IIa	n/a	CE 542056 NB 2797

Stop Washers	Class IIa	n/a	CE 542056 NB 2797
Bone Awl	Class I devices that qualify as re-usable surgical instruments	n/a	n/a Device did not require a Notified Body certificate under Directives
Broach, surgical, orthopaedic			
Cartilage Removal Instrument			
Countersink			
Distractor, Orthopaedic			
Drills/Taps			
Extractor/driver, surgical			
Gauge, depth			
Guide, surgical, instrument			
Impactor			
Orthopaedic chisel			
Orthopaedic reamer			
Protector, surgical instrument			
Screwdriver, bone			
Sizer/Trial			
Forceps			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/06/04	US_018334_2024_01	Initial issue
2024/09/26	US_018334_2024_02	Addition of the contract details