TERATECH Corporation
77-79 Terrace Hall Avenue
Burlington, Massachusetts 01803-
United States

April 24, 2024

Notified Body Confirmation Letter
Reference: 41313831-02 - CN00552-01

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, Intertek Medical Notified Body AB, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2862 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:

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Organisation ID (DUNS, Tax ID or equivalent): 04-3214575

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withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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,

Brian Mather
Certification Manager
Intertek Medical Notified Body AB

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
852698007096JW/ 12L5A Transducer	IIa	N/A	41313831-02 NB:0413
852698007003HV/ 15L4 Transducer	IIa	N/A	41313831-02 NB:0413
852698007140J8/15L4A Transducer	IIa	N/A	41313831-02 NB:0413
852698007522JS/15WL4 (50mm) Linear Wide Transducer	IIa	N/A	41313831-02 NB:0413
852698007072JG/16HL7 Transducer	IIa	N/A	41313831-02 NB:0413
852698007027JB/4V2A transducer	IIa	N/A	41313831-02 NB:0413
852698007010HS/5C2A Transducer	IIa	N/A	41313831-02 NB:0413
852698007409JV/8BP4 Bi-Plane	IIa	N/A	41313831-02 NB:0413
852698007058JN/8V3A Transducer	IIa	N/A	41313831-02 NB:0413
852698007065JK/9MC3 Transducer	IIa	N/A	41313831-02 NB:0413
852698007508JY/uSmart3200T Plus Ultrasound System without GPU, Tablet	IIa	N/A	41313831-02 NB:0413

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
852698007218JL/uSmart3200T Ultrasound System, Tablet USB3	IIa	N/A	41313831-02 NB:0413
852698007225JH/uSmart3300 Ultrasound System USB3	IIa	N/A	41313831-02 NB:0413
852698007539KB/XY Transducer	IIa	N/A	41313831-02 NB:0413

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

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action