

May 2024

Confirmation of receipt of formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR

**Re: Sheathing Technologies Inc.
Sheathes - Sterile Latex & Sterile Latex-Free Ultrasound Probe Covers,
accessories and Sterile Ultrasound Coupling Gel
NSAI Cert Number 252.811**

To whom it may concern

This letter confirms that National Standards Authority of Ireland (NSAI), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0050 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR from the following manufacturer:

**Sheathing Technologies, Inc.
675 Jarvis Drive, Morgan Hill, California, USA 95037**

The devices covered by the formal application are identified in the Table below.

NSAI anticipates that no later than 26 September 2024, the notified body and the manufacturer will have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII of MDR.

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

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- 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



Pamella Burdette Miller
European Medical Device Operations Manager
Medical Devices, NSAI

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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	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
Body-orifice ultrasound imaging transducer cover (sterile)	Class I S	n/a	252.811 NSAI 0050
Intraoperative ultrasound imaging transducer covers	Class IIa	n/a	252.811 NSAI 0050
Sterile ultrasound gel	Class I S	n/a	252.811 NSAI 0050