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Innomed, Inc
103 Estus Drive,
Savannah, GA 31404
United States of America

May 15, 2024

Confirmation Letter Reference: CLNB1639 – WW/MC/625853

To whom it may concern,

Confirmation of receipt 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, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 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:

Innomed, Inc
103 Estus Drive,
Savannah, GA 31404
United States of America
SRN Number: US-MF-000014761

Authorized representative
MediMark Europe
11 Rue Emile Zola
38100 Grenoble, France
SRN Number: FR-AR-000000182

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices 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93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

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 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st 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)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st 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 SGS Belgium NV NB1639,

Ian How
PP
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Global Medical Device Certification Manager
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Phone: +41 22 739 98 58

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	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
Extractor BASIC UDI-DI: 8402771INNOEXTRACT0188	Class I devices that qualify as re-usable surgical instruments.		N/A	Self-Certified Class I device (Declaration of Conformity drawn up prior to 26 May 2021) not requiring the involvement of a Notified Body under MDD but requiring it under MDR.
Forceps BASIC UDI-DI: 8402771INNOFORCEP01TM	Class I devices that qualify as re-usable surgical instruments.		N/A	Self-Certified Class I device (Declaration of Conformity drawn up prior to 26 May 2021) not requiring the involvement of a Notified Body under MDD but requiring it under MDR.
Curette BASIC UDI-DI: 8402771INNOCURET01ZB	Class I devices that qualify as re-usable surgical instruments.		N/A	Self-Certified Class I device (Declaration of Conformity drawn up prior to 26 May 2021)

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
				not requiring the involvement of a Notified Body under MDD but requiring it under MDR.
Awl BASIC UDI-DI: 8402771INNOAWL01K7	Class I devices that qualify as re-usable surgical instruments.		N/A	Self-Certified Class I device (Declaration of Conformity drawn up prior to 26 May 2021) not requiring the involvement of a Notified Body under MDD but requiring it under MDR.
Guide BASIC UDI-DI: 8402771INNOGUIDE01VS	Class I devices that qualify as re-usable surgical instruments.		N/A	Self-Certified Class I device (Declaration of Conformity drawn up prior to 26 May 2021) not requiring the involvement of a Notified Body under MDD but requiring it under MDR.
Impactor BASIC UDI-DI: 8402771INNOIMPACT01T2	Class I devices that qualify as re-		N/A	Self-Certified Class I device (Declaration of

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
	usable surgical instruments.			Conformity drawn up prior to 26 May 2021) not requiring the involvement of a Notified Body under MDD but requiring it under MDR.
Osteotome BASIC UDI-DI: 8402771INNOOSTEO016V	Class I devices that qualify as re-usable surgical instruments.		N/A	Self-Certified Class I device (Declaration of Conformity drawn up prior to 26 May 2021) not requiring the involvement of a Notified Body under MDD but requiring it under MDR.
Passer BASIC UDI-DI: 8402771INNOPASS01AG	Class I devices that qualify as re-usable surgical instruments.		N/A	Self-Certified Class I device (Declaration of Conformity drawn up prior to 26 May 2021) not requiring the involvement of a Notified Body under MDD but requiring it under MDR.

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
Probe BASIC UDI-DI: 8402771INNOPROBE0133	Class I devices that qualify as re-usable surgical instruments.		N/A	Self-Certified Class I device (Declaration of Conformity drawn up prior to 26 May 2021) not requiring the involvement of a Notified Body under MDD but requiring it under MDR.
Rasp BASIC UDI-DI: 8402771INNORASP01AT	Class I devices that qualify as re-usable surgical instruments.		N/A	Self-Certified Class I device (Declaration of Conformity drawn up prior to 26 May 2021) not requiring the involvement of a Notified Body under MDD but requiring it under MDR.
Retractor BASIC UDI-DI: 8402771INNORETRACT016A	Class I devices that qualify as re-usable surgical instruments.		N/A	Self-Certified Class I device (Declaration of Conformity drawn up prior to 26 May 2021) not requiring the involvement of a Notified Body

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
				under MDD but requiring it under MDR.
Scissors BASIC UDI-DI: 8402771INNOSCIS01A7	Class I devices that qualify as re-usable surgical instruments.		N/A	Self-Certified Class I device (Declaration of Conformity drawn up prior to 26 May 2021) not requiring the involvement of a Notified Body under MDD but requiring it under MDR.
Bone Hook BASIC UDI-DI: 8442771INNOHOOK019W	Class I devices that qualify as re-usable surgical instruments.		N/A	Self-Certified Class I device (Declaration of Conformity drawn up prior to 26 May 2021) not requiring the involvement of a Notified Body under MDD but requiring it under MDR.
Cover BASIC UDI-DI: 8402771INNOCOV01KP	Class I devices that qualify as re-usable surgical instruments.		N/A	Self-Certified Class I device (Declaration of Conformity drawn up prior to 26 May 2021)

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
				not requiring the involvement of a Notified Body under MDD but requiring it under MDR.

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/15	Version 1	Initial issue
2024/06/05	Version 2	Corrected the BASIC UDI-DI of Rasp