

**Malvern Medical Developments Ltd**  
Worcester  
WR3 8BP  
UK

09/05/2023

**Confirmation Letter Reference: CLNB1639 GBPC08783**

To whom it may concern,

**Confirmation of receipt of a formal application and conclusion of written agreement 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:

**Malvern Medical Developments Ltd**  
Worcester  
WR3 8BP  
UK  
SRN Number (if available): GB-MF-000014481

EU Rep:

**Advena Limited.**  
Tower Business Centre, 2nd Flr;  
Tower Street,  
Swatar, BKR 4013  
Malta  
SRN: MT-AR-000000234

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;

- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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:

- 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 SGS Belgium NV 1639,



Virginie SILORET  
Global Medical Device Certification Manager  
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Phone : +41 22 739 98 58

**Devices covered by this letter:**

Device name / 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
- Sterile: Bladder, Anorectal Manometry and Urodynamic Catheters -Bladder and Urodynamic Catheter Sets and catheter Accessories (extension lines, pump tube sets, voiding adaptor, set guard, Y	Class IIa	N/A	GB19/964512; NB1639

Device name / 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
connector, fir tree connectors, coloured manometer line),  Non Sterile -Gastrointestinal oesophageal catheters - Anorectal manometry catheters  506016652rectal97 506016652oesophageal3Y 506016652urodynamicX8 506016652pumptube8H 506016652accessoriesHS			
Annex V Sterility Aspects only: Restricted to the aspects of manufacture concerned with securing an maintaining sterile conditions. Sterile saliva collection kit 506016652saliva9R	Class Is	N/A	GB19/964512; NB1639

#### Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/05/09	Version 1	Initial issue