EC Certificate Production Quality Assurance System: Certificate GB19/964231

The management system of

Medfor Products Ltd

Unit 2, Gresham Industrial Estate, Eastern Road,
Aldershot, Hampshire, GU12 4YD, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Sterile and non sterile containers for the transit and storage of human organs and tissues prior to transplantation.

For placing on the market of Class IIb covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 31 October 2019 until 19 December 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 17 September 2001.
and first certified by SGS Belgium on 31 October 2019.

Certification is based on reports numbered GB/PC 200659

Authorised by

Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639
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Medfor Products Ltd
Unit 2, Gresham Industrial Estate
Eastern Road, ALDERSHOT
GU12 4YD
UK

18/01/2024

Confirmation Letter Reference: CLNB1639 GBPC 200659

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:

Medfor Products Ltd
Unit 2, Gresham Industrial Estate
Eastern Road, ALDERSHOT
GU12 4YD
UK
SRN: GB-MF-000022996

Authorised representative:

Emergo Europe
Westervoortsedijk
60 6827 AT Arnhem
The Netherlands
SRN: NL-AR-000000116

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
Email: Virginie.siloret@sgs.com
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 and non sterile containers for the transit and storage of human organs and tissues prior to transplantation. 506056603MDDE6	Class IIa	N/A	GB19/964231; NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
18/01/2024	Version 1	Initial issue
26/01/2024	Version 2	Baisc UDI-DI changed: From: Sterile and non sterile containers for the transit and storage of human organs and tissues prior to transplantation. 506056603C1EO2J 506056603C2GAZW 506056603C3NS3X To: Sterile and non sterile containers for the transit and storage of human organs and tissues prior to transplantation. 506056603MDDE6