

EC-Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Microtek Medical Malta Ltd.
Sorbonne Centre F20 - Mosta Technopark
MST 3000 Mosta
Malta

has introduced, applies and maintains a Quality Assurance System for the aspects of manufacture **concerned with securing and maintaining sterile conditions** for the products / product categories:

Equipment Drapes

The compliance of the Quality Assurance System with the below mentioned requirements of the **Council Directive 93/42/EEC** was verified by an audit:

Annex V

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 19 April 2023

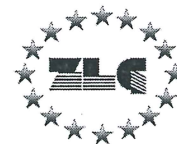
Report No.: 2620FS19F
Process No.: QS - 2620
Certificate No.: 2620GB415180704

Hamburg, 04 July 2018



MEDCERT Certification Body
(Dr. Andreas Schich)

MEDCERT Identification No.: 0482



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15



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Sorbonne Centre F20 – Mosta Technopark
MST 3000 Mosta
Malta

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Pilatuspool 2
20355 Hamburg
Germany

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Date: 2023-05-12
Our reference: QS - 2620

Notified Body Confirmation Letter
Reference: N/A

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, DNV Medcert GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0482 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.

Microtek Medical Malta Ltd.
Sorbonne Centre F20 – Mosta Technopark
MST 3000 Mosta
Malta
SRN Number: MT-MF-000012827

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; 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,

Lorenz Runge
Chief Certification

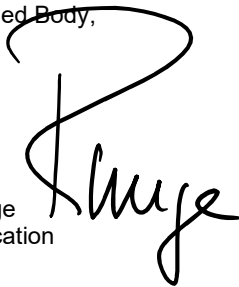


Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

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
Equipment Drapes	Class I devices placed on the market in sterile condition custom-made device	N/A	Certificate 2620GB415180704; NB0482
Probe Covers	Class IIa	N/A	Certificate 2620GB414210519A; NB0482

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
none	none	none	none

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/05/12	N/A	Initial issue