

TÜV NORD Polska Sp. z o.o.
ul. Mickiewicza 29
40-085 Katowice
Poland

METRUM CRYOFLEX Spółka z ograniczoną
odpowiedzialnością
ul. Zielna 29
05-082 Blizne Łaszczyńskiego
Poland

Notified Body Confirmation Letter
Reference: 1/23/3

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, TÜV NORD Polska Sp. z o.o., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2274 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:

METRUM CRYOFLEX Spółka z ograniczoną odpowiedzialnością
ul. Zielna 29
05-082 Blizne Łaszczyńskiego
Poland
SRN Number: PL-MF-000022624

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for 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.



DLA NASZEJ WSPÓLNEJ PRZYSZŁOŚCI TÜV NORD POLSKA PROWADZI NASADZENIA NOWYCH DRZEW I UŻYWA PAPIERU BIUROWEGO Z RECYKLINGU.

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www.tuv-nord.pl

Zarząd:

Dagmara Żygowska - Prezes Zarządu

NIP 634-10-14-590
REGON: 272557766

Sąd Rejonowy w Katowicach, KRS: 0000118633
Kapitał zakładowy: 850000 PLN

Konto bankowe:

mBank o. korporacyjny Katowice
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EUR 72 1140 1078 0000 4042 4600 1002
USD 93 1140 1078 0000 4042 4600 1012

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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,

Katarzyna Jochymczyk
Medical Devices Certification Specialist

Jowita Dyrda
Deputy Head of the Notified Body No. 2274 for Medical Devices
TÜV NORD Polska Sp. z o.o.



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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 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
Lymphatic drainage and compression massage apparatus Boa max 2 Basic UDI-DI 590755922006GN	Class IIb	N/A	Certificate; TNP/MDD/0276/2075/2019 TÜV NORD Polska Sp. z o.o. No. 2274
Cryosurgery unit CRYO-S Mini Basic UDI-DI 590755922000GA	Class IIb	Device for cryosurgery with cryoprobes and ligators, without the function or with the function for localization of the nerve CRYO-S Mini	Certificate; TNP/MDD/0276/2075/2019 TÜV NORD Polska Sp. z o.o. No. 2274
Reusable probes for cryosurgery Basic UDI-DI: 590755922CPSRM5	Class IIb		
Cryosurgery unit CRYO-S Electric II Basic UDI-DI 590755922087HG	Class IIb	Device for cryosurgery with cryoprobes and ligators, without the function or with the function for localization of the nerve CRYO-S Electric II	Certificate; TNP/MDD/0276/2075/2019 TÜV NORD Polska Sp. z o.o. No. 2274
Reusable probes for cryosurgery Basic UDI-DI: 590755922CPSRM5	Class IIb		
Cryosurgery unit CRYO-S Painless Basic UDI-DI 590755922068HC	Class IIb	Device for cryosurgery with cryoprobes and ligators, without the function or with the function	Certificate; TNP/MDD/0276/2075/2019 TÜV NORD Polska Sp. z o.o.



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Disposable probe for cryoanalgesia / cryoneurolysis Basic UDI-DI 590755922CPPDKY	Class IIb	for localization of the nerve CRYO-S Painless	No. 2274
Reusable probes for cryoanalgesia/cryoneurolysis Basic UDI-DI 590755922CPPRLU	Class IIb		
Cryotherapy and cryostimulation unit CRYO-T Duo Basic UDI-DI 590755922146H7	Class IIa	N/A	Certificate; TNP/MDD/0276/2075/2019 TÜV NORD Polska Sp. z o.o No. 2274
Cryotherapy and cryostimulation unit CRYO-T Elephant mini GM Basic UDI-DI 590755922082H6	Class IIa	N/A	Certificate; TNP/MDD/0276/2075/2019 TÜV NORD Polska Sp. z o.o No. 2274
Surgical diode laser SWING 12 Basic UDI-DI 59075592235829E	Class IIb	N/A	Certificate; TNP/MDD/0276/2075/2019 TÜV NORD Polska Sp. z o.o No. 2274
Surgical diode laser SWING 15 Basic UDI-DI 59075592235829E	Class IIb	N/A	Certificate; TNP/MDD/0276/2075/2019 TÜV NORD Polska Sp. z o.o No. 2274



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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
Surgical diode laser TWIST Diode Basic UDI-DI 590755922338HJ	Class IIb	N/A	Certificate; TNP/MDD/0276/2075/2019 TÜV NORD Polska Sp. z o.o No. 2274

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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
17.11.2023	Version 1	Initial issue
20.11.2023	Version 2	Correction of the producer name
12.11.2024	1/23/2	Correction of the certificate number. Withdrawal of the following devices from MDR certification: Arctica Classic mini, Arctica Classic mini with an anteroom, CRYO-T 2, CRYO-T Elephant G, CRYO-T Cooler. Addition of generic names for medical devices. Clarifying the status of probes.



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