

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

**Enbio Group AG**  
Eichengasse 3  
4702 Oensingen  
Switzerland

**Notified Body Confirmation Letter**  
**Reference: 07/24**

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:

**Enbio Group AG**  
Eichengasse 3  
4702 Oensingen  
Switzerland  
SRN Number: CHRN-MF-20001662

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

The transition timeline 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) is 31 December 2028.



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

**TÜV NORD Polska Sp. z o. o.**

ul. Mickiewicza 29  
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biuro@tuv-nord.pl  
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  
02 1140 1078 0000 4042 4600 1001  
EUR 72 1140 1078 0000 4042 4600 1002  
USD 93 1140 1078 0000 4042 4600 1012

On behalf of the Notified Body,

Jowita Dyrda

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

**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
Enbio S BASIC UDI-DI: 7629999sterilizersM2	Class IIa	N/A	Certificate No. TNP/MDD/0387/4780/2021  TÜV NORD Polska Sp. z o.o No. 2274
Enbio PRO BASIC UDI-DI: 7629999sterilizersM2	Class IIa	N/A	Certificate No. TNP/MDD/0387/4780/2021  TÜV NORD Polska Sp. z o.o No. 2274

## Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
6.06.2024	Version 1	Initial issue



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