TÜVNORD

Katowice, 22.10.2024

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

Medical Brokers Adam Cieślak Sp. j.
Lipowa 1
95-100 Zgierz
Poland

Notified Body Confirmation Letter
Reference: 52/24/1

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:

Medical Brokers Adam Cieślak Sp. j.
Lipowa 1
95-100 Zgierz
Poland

SRN number: PL-MF-000024347

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.

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:

- 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

TÜVNORD

On behalf of the Notified Body,

Digitally signed
by Filip Wójcik
Date: 2024.12.13
09:37:48 +01'00'

Medical Devices Certification Specialist

2024.12.13
09:30:39
+01'00'

Kornel Lukaszczyk
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**
Sterylne igły do endoirygacji/ Sterile endoirrigation needles - Medical Brokers Basic UDI-DI: 5904310219iglyendoVE	Class IIa	N/A	Certificate: TNP/MDD/0305/3540/2020 NB: 2274
Sterylne kaniule dermatologiczne/ Sterile cannulas for dermatology - Medical Brokers - Dermasculpt - Vida Bela Basic UDI-DI: 5904310219kaniuleVV	Class IIa	N/A	Certificate: TNP/MDD/0305/3540/2020 NB: 2274
Sterylne igły do mezoterapii/ Sterile mesotherapy needles - Meso needles Basic UDI-DI:	Class IIa	N/A	Certificate: TNP/MDD/0305/3540/2020 NB: 2274

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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

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
5904310219iglymezoXT			

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
2024/12/13	52/24/1	Initial issue

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