POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

KW/MC/2024/0275

Warsaw, 21.06.2024

ChM sp. z o.o.

Lewickie 3b
16-061 Juchnowiec Kościelny
POLAND

Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application 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, Polish Centre for Testing and Certification, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1434 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR with the following manufacturer:

ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Kościelny
POLAND
SRN Number: PL-MF-000002121

The devices covered by the formal application mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received 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 but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

POLISH CENTRE FOR
TESTING AND CERTIFICATION

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

Tomasz Koeber

Tomasz Koeber

Head of Medical Device Certification Department

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
Resorbable Implants Basic UDI-DI: 590844755P64W	Class III	Mikrosystemy biowchłanialne do chirurgii twarzowo-szczękowej	1434-MDD-224/2020, NB 1434; 1434-MDD-225/2020, NB 1434
Hip Joint Endoprosthesis Basic UDI-DI: 59084475SP54U	Class III	N/A	1434-MDD-345/2021, NB 1434; 1434-MDD-346/2021, NB 1434

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
21.06.2024	KW/MC/2024/0275	Initial issue