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MEDGAL[®]
ORTHOPAEDIC IMPLANTS & INSTRUMENTS

Białystok, 10-03-2016

OSTECA, UAB
Danes str. 47,
Klaipeda
LITHUANIA

TO WHOM IT MAY CONCERN

LETTER OF AUTHORIZATION

This is to certify that:

OSTECA, UAB
Danes str. 47,
LT-92108 Klaipeda,
LITHUANIA

is authorized and has an exclusive right to distribute the MEDGAL production such like osteosynthesis implants, hip joint prostheses, tools, instruments and other production

This authorization letter is valid for an indefinite period.

CEO

Urszula Borowska-Skarżyńska

Bialystokas, 10.03.2016

UAB „OSTECA“
Danės g. 47,
Kretinga
Lietuva

Tai kam tai gali būti aktualu,

ĮGALIOJIMAS

Tai patvirtinta, kad

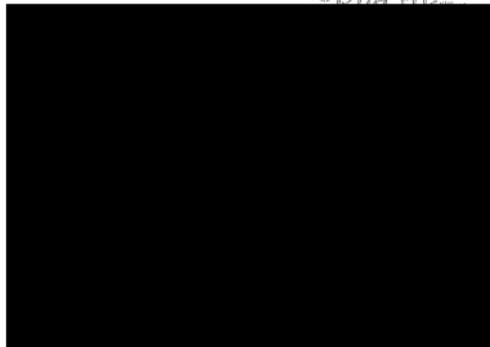
UAB „OSTECA“
Danės g. 47,
LT-92105 Klaipėda
Lietuva

yra įgaliotas ir turi išimtinę teisę, platinti *Medgal* produkciją: osteosintezės implantus, klubo sąnario protezus, įrankius, instrumentus ir kitus gaminius išskirtinėmis teisėmis Lietuvos rinkoje.

Šis įgaliojimas galioja neapibrėžtą laiko tarpą.

CEO
Urszula Borowska-Skarzynska

Kopija tikras



inikas
Ročys

mas tikras

Verslo srauto produktai
Sertifikavimo skyrius

TUV Rheinland LGA Products GmbH, 51105 Kiolnas

Medgal Sp. z o.o.
Niewodnicka g. 26a
16-001 Księżyńo
Lenkija

Notifikuojančios įstaigos patvirtinimo raštas

Nuoroda: PLA_HZ_2024-05-21

Tam, kam tai gali būti aktualu,

Oficialaus prašymo statuso patvirtinimas, rašytinis susitarimas ir tinkama priežiūra pagal Reglamentą ES 2023/607 iš dalies keičiantį reglamentus (ES) 2017/745 ir (ES) 2017/746 dėl pereinamojo laikotarpio nuostatos tam tikriems medicinos prietaisams ir in vitro medicininių priemonių diagnostikai

Šis raštas patvirtina, kad notifikuotoji įstaiga TÜV Rheinland LGA Products GmbH (NB), priskirta pagal Reglamentą (ES) 2017/745 (MDR) ir identifikuojama numeriu 0197 NANDO sistemoje, gavo oficialų prašymą pagal MDR VII priedo 4.3 skirsnio pirmą pastraipą ir pasirašė rašytinį susitarimą pagal MDR VII priedo 4.3 skirsnio antrąją pastraipą su šiuo gamintoju:

Medgal Sp. z o.o.
Niewodnicka g. 26a
16-001 Księżyńo
Lenkija
SRN numeris (jei galimas): vyksta

Priemonės, kurioms pateikta oficiali paraiška ir nurodytas rašytinis susitarimas nurodytos toliau pateiktose lentelėse. 1 lentelėje nurodytos priemonės, kurioms MDR paraiška gauta, sudaryta rašytinė sutartis ir dėl kurios NB taip pat yra atsakinga už tinkamą priežiūrą pagal taikomą direktyvą. 2 lentelėje nurodytos priemonės, kurioms buvo gauta MDR paraiška ir sudaryta rašytinė sutartis, tačiau NB atsakomybės dar neprisiėmė tinkamai prižiūrėti atitinkamus prietaisus pagal taikomus reikalavimus direktyvą.

Priemonėms, kurioms yra neatšauktos, ir kurioms išduoti sertifikatai pagal Direktyvą 90/385/EEB (AIMDD) arba Direktyvą 93/42/EEB (MDD), kuri nustojo galioti po 2021 m. gegužės 26 d., tačiau anksčiau nei 2023 m. kovo 20 d., šis raštas taip pat patvirtina, jog gamintojas arba pasirašė rašytinį susitarimą pagal MDR iki MDD/AIMDD sertifikato galiojimo pabaigos, arba pateikė įrodymų, kad valstybės narės kompetentinga institucija buvo suteikusi

leidžiančią nukrypti nuostatą arba atleisti nuo taikytinos atitikties vertinimo procedūros pagal MDR 59 straipsnio 1 dalį arba 97 straipsnio 1 dalį MDR atitinkamai iki 2023 m. kovo 20 d. atitinkamiems įrenginiams.

Pereinamieji terminai, taikomi priemonėms, kurioms taikomas šis raštas, atsižvelgiant į tai, kad gamintojas nuolat laikosi kitų straipsnyje nurodytų sąlygų MDR 120.3c (su pakeitimais, padarytais (ES) 2023/607), pateikiami toliau:

- 2026 m. gegužės 26 d. III klasės pagal užsakymą pagamintiems implantuojamiems prietaisams
- 2027 m. gruodžio 31 d. III klasės prietaisams ir IIb klasės implantuojamiems prietaisams, išskyrus nusistovėjusias technologijas (tokias kaip siūlai, kabės, odontologinės plombos, dantų breketai, dantų vainikėliai, varžtai, pleištai, plokštelės, laidai, kaiščiai, spaustukai ir jungtys)
- 2028 m. gruodžio 31 d. kitiems IIb klasės, IIa klasės, I klasės priemonėms, kurios į rinką pateikiamos sterilios arba turi matavimo funkciją.
- 2028 m. gruodžio 31 d. įrenginiams, kuriems pagal MDD nereikalingas notifikuojančiosios įstaigos įsikišimas, bet pagal MDR jis reikalingas (pvz., I klasės įrenginiai, kurie kvalifikuojami kaip pakartotinai naudojami chirurginiai instrumentai)

Notifikuojančiosios įstaigos vardu

Pasirašyta el. parašu

Daniel Swiatko

Data: 2024-05-22

TÜV Rheinland LGA Products GmbH • 51105 Köln

Medgal Sp. z o.o.
ul. Niewodnicka 26a
16-001 Księżyno
Poland

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date May 22, 2024

Notified Body Confirmation Letter

Reference. : PLA_HZ_2024-05-21

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 Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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:

Medgal Sp. z o.o.
ul. Niewodnicka 26a
16-001 Księżyno
Poland
SRN Number (if available): In progress

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 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 May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either 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 March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

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Board of Management

Dipl.-Ing.
Thomas Weigand, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 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)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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

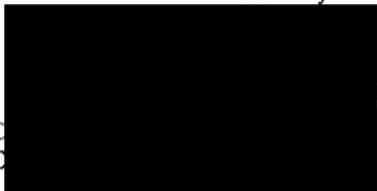
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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

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
Gwoździe śródszpikowe blokowane udowe Basic UDI-DI: 5904992-TF01-0001-KG	Class IIb implantable (WET)	Femur nail, non-sterile (GMDN 56643)	HD 60144470 0001; 0197
Gwoździe śródszpikowe blokowane udowe sterylne Basic UDI-DI: 5904992-TF01-0002-KK	Class IIb implantable (WET)	Femur nail, non-sterile (GMDN 56643)	HD 60144470 0001; 0197
Gwoździe śródszpikowe blokowane udowe pokryte Si-DLC Basic UDI-DI: 5904992-TF01-0003-KN	Class IIb implantable (WET)	Femur nail, non-sterile (GMDN 56643)	HD 60144470 0001; 0197
Gwoździe śródszpikowe blokowane do kończyn górnych Basic UDI-DI: 5904992-TF01-0005-KU	Class IIb implantable (WET)	Humerus nail, sterile (GMDN 38153)	HD 60144470 0001; 0197

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
Gwoździe śródszpikowe blokowane do kończyn górnych sterylne Basic UDI-DI: 5904992-TF01-0006-KX	Class IIb implantable (WET)	Humerus nail, sterile (GMDN 38153)	HD 60144470 0001; 0197
Gwoździe śródszpikowe blokowane do kończyn górnych Si-DLC Basic UDI-DI: 5904992-TF01-0007-L2	Class IIb implantable (WET)	Humerus nail, non-sterile (GMDN 38153)	HD 60144470 0001; 0197
Gwoździe śródszpikowe blokowane piszczelowe Basic UDI-DI: 5904992-TF01-0009-L8	Class IIb implantable (WET)	Tibia nail non-sterile (GMDN 38152)	HD 60144470 0001; 0197
Gwoździe śródszpikowe blokowane piszczelowe sterylne Basic UDI-DI: 5904992-TF01-0010-KJ	Class IIb implantable (WET)	Tibia nail non-sterile (GMDN 38152)	HD 60144470 0001; 0197
Gwoździe śródszpikowe blokowane piszczelowe Si-DLC Basic UDI-DI: 5904992-TF01-0011-KM	Class IIb implantable (WET)	Tibia nail non-sterile (GMDN 38152)	HD 60144470 0001; 0197
Gwoździe do artrodezy Basic UDI-DI: 5904992-TF01-0013-KT	Class IIb implantable (WET)	Humerus nail, non-sterile Tibia nail non-sterile Femur nail, non-sterile (GMDN 56643; 38152; 38153)	HD 60144470 0001; 0197
Gwoździe do artrodezy sterylne Basic UDI-DI: 5904992-TF01-0014-KW	Class IIb implantable (WET)	Humerus nail, non-sterile Tibia nail non-sterile Femur nail, non-sterile (GMDN 56643; 38152; 38153)	HD 60144470 0001; 0197
Gwoździe do artrodezy Si-DLC Basic UDI-DI: 5904992-TF01-0015-KZ	Class IIb implantable (WET)	Humerus nail, non-sterile Tibia nail non-sterile Femur nail, non-sterile (GMDN 56643; 38152; 38153)	HD 60144470 0001; 0197
Akcesoria do gwoździ Basic UDI-DI: 5904992-TF01-0017-L7	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, non-sterile (GMDN 56642)	HD 60144470 0001; 0197

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
Akcesoria do gwoździ sterylne Basic UDI-DI: 5904992-TF01-0018-LA	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, sterile (GMDN 46646)	HD 60144470 0001; 0197
Akcesoria do gwoździ Si-DLC Basic UDI-DI: 5904992-TF01-0019-LD	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, non-sterile (GMDN 56642)	HD 60144470 0001; 0197
Płytki kostne do kończyny górnej Basic UDI-DI: 5904992-TF03-0001-LJ	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki kostne do kończyny górnej sterylne Basic UDI-DI: 5904992-TF03-0002-LM	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki kostne do kończyny górnej Si-DLC Basic UDI-DI: 5904992-TF03-0003-LQ	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki do dłoni Basic UDI-DI: 5904992-TF03-0005-LW	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki do dłoni sterylne Basic UDI-DI: 5904992-TF03-0006-LZ	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki do dłoni Si-DLC Basic UDI-DI: 5904992-TF03-0007-M4	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki do klatki piersiowej Basic UDI-DI: 5904992-TF03-0009-MA	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki do klatki piersiowej sterylne Basic UDI-DI: 5904992-TF03-0010-LL	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki do klatki piersiowej Si-DLC Basic UDI-DI: 5904992-TF03-0011-LP	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki do miednicy	Class IIb	Orthopaedic fixation plate, non-	HD 60144470 0001;

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
Basic UDI-DI: 5904992-TF03-0013-LV Płytki do mednicy sterylne	implantable (WET)	bioabsorbable (GMDN 46647)	0197
Basic UDI-DI: 5904992-TF03-0014-LY Płytki do mednicy Si-DLC	Class IIb implantable (WET)	Orthopaedic fixation plate, non- bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF03-0015-M3 Płytki udowe DHS/DCS	Class IIb implantable (WET)	Orthopaedic fixation plate, non- bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF03-0017-M9 Płytki udowe DHS/DCS sterylne	Class IIb implantable (WET)	Orthopaedic fixation plate, non- bioabsorbable (GMDN 46647; GMDN 34003)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF03-0018-MC Płytki udowe DHS/DCS Si- DLC	Class IIb implantable (WET)	Orthopaedic fixation plate, non- bioabsorbable (GMDN 46647; GMDN 34003)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF03-0019-MF Płytki ostrzowe	Class IIb implantable (WET)	Orthopaedic fixation plate, non- bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF03-0021-LU Płytki ostrzowe sterylne	Class IIb implantable (WET)	Orthopaedic fixation plate, non- bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF03-0022-LX Płytki ostrzowe Si-DLC	Class IIb implantable (WET)	Orthopaedic fixation plate, non- bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF03-0023-M2 Płytki do podudzia	Class IIb implantable (WET)	Orthopaedic fixation plate, non- bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF03-0025-M8 Płytki do podudzia sterylne	Class IIb implantable (WET)	Orthopaedic fixation plate, non- bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF03-0026-MB Płytki do podudzia Si-DLC	Class IIb implantable (WET)	Orthopaedic fixation plate, non- bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF03-0027-ME Płytki do stopy	Class IIb implantable (WET)	Orthopaedic fixation plate, non- bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Basic UDI-DI:	Class IIb implantable (WET)	Orthopaedic fixation plate, non- bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197

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
5904992-TF03-0029-ML		bioabsorbable (GMDN 46647)	
Płytki do stopy sterylne Basic UDI-DI: 5904992-TF03-0030-LW	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki do stopy Si-DLC Basic UDI-DI: 5904992-TF03-0031-LZ	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki do twarzoczaszki Basic UDI-DI: 5904992-TF03-0033-M7	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki do twarzoczaszki sterylne Basic UDI-DI: 5904992-TF03-0034-MA	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki do twarzoczaszki Si-DLC Basic UDI-DI: 5904992-TF03-0035-MD	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki do artrodezy Basic UDI-DI: 5904992-TF03-0037-MK	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki do artrodezy sterylne Basic UDI-DI: 5904992-TF03-0038-MN	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki do artrodezy Si-DLC Basic UDI-DI: 5904992-TF03-0039-MR	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki uniwersalne Basic UDI-DI: 5904992-TF03-0041-M6	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki uniwersalne sterylne Basic UDI-DI: 5904992-TF03-0042-M9	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Płytki uniwersalne Si-DLC Basic UDI-DI: 5904992-TF03-0043-MC	Class IIb implantable (WET)	Orthopaedic fixation plate, non-bioabsorbable (GMDN 46647)	HD 60144470 0001; 0197
Akcesoria do płytek Basic UDI-DI: 5904992-TF03-0045-MJ	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, non-sterile (GMDN 56642)	HD 60144470 0001; 0197

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
Akcesoria do płytek sterylne Basic UDI-DI: 5904992-TF03-0046-MM	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, sterile (GMDN 46646)	HD 60144470 0001; 0197
Akcesoria do płytek Si-DLC Basic UDI-DI: 5904992-TF03-0047-MQ	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, non-sterile (GMDN 56642)	HD 60144470 0001; 0197
Wkręty kostne Basic UDI-DI: 5904992-TF02-0001-KZ	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, non-sterile (GMDN 56642)	HD 60144470 0001; 0197
Wkręty kostne sterylne Basic UDI-DI: 5904992-TF02-0002-L4	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, sterile (GMDN 46646)	HD 60144470 0001; 0197
Wkręty kostne Si-DLC Basic UDI-DI: 5904992-TF02-0003-L7	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, non-sterile (GMDN 56642)	HD 60144470 0001; 0197
Wkręty kostne blokowane Basic UDI-DI: 5904992-TF02-0005-LD	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, non-sterile (GMDN 56642)	HD 60144470 0001; 0197
Wkręty kostne blokowane sterylne Basic UDI-DI: 5904992-TF02-0006-LG	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, sterile (GMDN 46646)	HD 60144470 0001; 0197
Wkręty kostne blokowane Si-DLC Basic UDI-DI: 5904992-TF02-0007-LK	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, non-sterile (GMDN 56642)	HD 60144470 0001; 0197
Wkręty zrywane Basic UDI-DI: 5904992-TF02-0009-LR	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, non-sterile (GMDN 56642)	HD 60144470 0001; 0197
Wkręty zrywane sterylne Basic UDI-DI: 5904992-TF02-0010-L3	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, sterile (GMDN 46646)	HD 60144470 0001; 0197
Wkręty zrywane Si-DLC Basic UDI-DI:	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable,	HD 60144470 0001; 0197

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
5904992-TF02-0011-L6		non-sterile (GMDN 56642)	
Wkręty twarozczaszkowe sterylne	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, sterile (GMDN 46646)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF02-0014-LF			
Wkręty twarozczaszkowe Si-DLC	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, non-sterile (GMDN 56642)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF02-0015-LJ			
Wkręty do artroskopii	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, non-sterile (GMDN 56642)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF02-0017-LQ			
Wkręty do artroskopii Si-DLC	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, sterile (GMDN 46646)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF02-0018-LT			
Wkręty do artroskopii sterylne	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, non-sterile (GMDN 56642)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF02-0019-LW			
Akcesoria do wkrętów	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, non-sterile (GMDN 56642)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF02-0021-LB			
Akcesoria do wkrętów Si-DLC	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, sterile (GMDN 46646)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF02-0022-LE			
Akcesoria do wkrętów sterylne	Class IIb implantable (WET)	Orthopaedic bone screws, non-bioabsorbable, non-sterile (GMDN 56642)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF02-0023-LH			
Gwoździe śródszpikowe	Class IIb implantable (WET)	Flexible bone nail (GMDN 61154)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF01-0021-KS			
Gwoździe śródszpikowe sterylne	Class IIb implantable (WET)	Flexible bone nail (GMDN 61154)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF01-0022-KV			
Gwoździe śródszpikowe Si-DLC	Class IIb	Flexible bone nail (GMDN 61154)	HD 60144470 0001;

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
Basic UDI-DI: 5904992-TF01-0023-KY	implantable (WET)		0197
Kirschnery/groty/grotowkręty	Class IIb implantable (WET)	Orhopeadic bone wire; Orthopaedic pin (GMDN 35685; GMDN 32854)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF01-0025-L6			
Kirschnery/groty/grotowkręty sterylne	Class IIb implantable (WET)	Orhopeadic bone wire; Orthopaedic pin (GMDN 35685; GMDN 32854)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF01-0026-L9			
Kirschnery/groty/grotowkręty Si-DLC	Class IIb implantable (WET)	Orhopeadic bone wire; Orthopaedic pin (GMDN 35685; GMDN 32854)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF01-0027-LC			
Wyroby do cerkłażu	Class IIb implantable (WET)	Orhopeadic bone wire; Orthopaedic pin (GMDN 35685; GMDN 32854)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF01-0029-LJ			
Wyroby do cerkłażu sterylne	Class IIb implantable (WET)	Orhopeadic bone wire; Orthopaedic pin (GMDN 35685; GMDN 32854)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF01-0030-KU			
Wyroby do cerkłażu Si-DLC	Class IIb implantable (WET)	Orhopeadic bone wire; Orthopaedic pin (GMDN 35685; GMDN 32854)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF01-0031-KX			
Klamry	Class IIb implantable (WET)	Bone staple (GMDN 16103)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF01-0033-L5			
Klamry sterylne	Class IIb implantable (WET)	Bone staple (GMDN 16103)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF01-0034-L8			
Klamry Si-DLC	Class IIb implantable (WET)	Bone staple (GMDN 16103)	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF01-0035-LB			
Zestawy zabiegowe	Class IIb implantable (WET)	Bone drill, bone cutter, bone tap, bone countersink	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF18-0001-PS			
Wiertła i frezy	Class IIb implantable (WET)	Bone drill, bone cutter, bone tap, bone countersink	HD 60144470 0001; 0197
Basic UDI-DI: 5904992-TF-06-0001-R2			
Adaptory do aktywnych wyrobów	Class IIb implantable (WET)	Guide wire for ortopaedic application; Kirschner wire	HD 60144470 0001; 0197
Basic UDI-DI:			

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
5904992-TF-06-0002-R5			

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
Celowniki ze stopu metalu Basic UDI-DI: 5904992-TF-07-0001-RK	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Celowniki kompozytowe Basic UDI-DI: 5904992-TF-07-0002-RN	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Celowniki ze stopu metalu połączonych z tworzywem Basic UDI-DI: 5904992-TF-07-0003-RR	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Celowniki ze stopów metalu połączonych z kompozytem węglowym Basic UDI-DI: 5904992-TF-07-0004-RU	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Celowniki ze stopów metalu połączonych z kompozytem węglowym oraz polimerami Basic UDI-DI: 5904992-TF-07-0005-RX	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Narzędzia do wprowadzania i wyciągania wyrobów - ze stopów metalu Basic UDI-DI:	Class Ir	N/A	Notified body involvement not required pursuant to MDD

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
5904992-TF-07-0006-S2 Narzędzia do wprowadzania i wyciągania wyrobów - tworzywa sztuczne	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0007-S5 Narzędzia do wprowadzania i wyciągania wyrobów - ze stopów metalu i tworzywa sztuczne	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0008-S8 Instrumentaria do przygotowania wyrobów - ze stopu metalu	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0009-SB Instrumentaria do przygotowania wyrobów - z tworzywa sztuczne	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0010-RM Instrumentaria do przygotowania wyrobów - ze stopu metalu połączone z tworzywem sztucznym	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0011-RQ Osteotomy ze stopów metalu	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0012-RT Osteotomy ze stopów metalu połączonych z polimerami	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0013-RW Wyżłabiacze ze stopu metalu	Class Ir	N/A	Notified body involvement not

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
Basic UDI-DI: 5904992-TF-07-0014-RZ Wyżłabiacze ze stopu metalu połączonych z tworzywem sztucznym	Class Ir	N/A	required pursuant to MDD Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0015-S4 Instrumentarium do cięcia ze stopu metalu	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0016-S7 Instrumentarium do cięcia ze stopu metalu połączonych z tworzywem sztucznym	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0017-SA Szczypcy - inne ze stopów metalu	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0018-SD Retraktory ze stopów metalu	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0019-SG Retraktory z tworzywa sztucznego	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0020-RS Retraktory ze stopów metalu połączonych z tworzywem	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0021-RV Instrumentaria do osteosyntezy - inne ze stopów metalu	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0022-RY Instrumentaria do osteosyntezy - inne z tworzywa sztucznego	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Basic UDI-DI: 5904992-TF-07-0023-S3			

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
Instrumentaria do osteosyntezy - inne z kompozytu węglowego Basic UDI-DI: 5904992-TF-07-0024-S6	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Instrumentaria do osteosyntezy - inne ze stopów metalu połączonych z tworzywem sztucznym Basic UDI-DI: 5904992-TF-07-0025-S9	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Instrumentaria do osteosyntezy - inne ze stopów metalu połączonych z tworzywem sztucznym Basic UDI-DI: 5904992-TF-07-0025-S9	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Instrumentaria do osteosyntezy - inne ze stopów metalu połączonych z tworzywem sztucznym oraz kompozytem węglowym Basic UDI-DI: 5904992-TF-07-0026-SC	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Dystraktory ze stopu metalu Basic UDI-DI: 5904992-TF-07-0027-SF	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Wkrętaki ze stopu metalu Basic UDI-DI: 5904992-TF-07-0028-SJ	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Wkrętaki ze stopu metalu połączonych z polimerami Basic UDI-DI: 5904992-TF-07-0029-SM	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Młotki ze stopu metalu Basic UDI-DI: 5904992-TF-07-0030-RX	Class Ir	N/A	Notified body involvement not required pursuant to MDD

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
Młotki ze stopu metalu połączonych z polimerami Basic UDI-DI: 5904992-TF-07-0031-S2	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Gwintowniki Basic UDI-DI: 5904992-TF-07-0032-S5	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Trokary Basic UDI-DI: 5904992-TF-07-0033-S8	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Frezy i wiertła Basic UDI-DI: 5904992-TF-07-0034-SB	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Szczypce redukcyjne Basic UDI-DI: 5904992-TF-07-0035-SE	Class Ir	N/A	Notified body involvement not required pursuant to MDD
Podważki Basic UDI-DI: 5904992-TF-07-0036-SH	Class Ir	N/A	Notified body involvement not required pursuant to MDD

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/22	1	Initial issue