Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

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Contact

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Date October 17, 2024

Notified Body Confirmation Letter
Reference. : ChM_PLA0_HZ_2024-04-15 replaced by ChM_PLA0_HZ_2024-07-18

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:

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

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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

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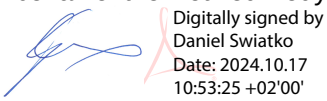
Chairman of the
Supervisory Board

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



Daniel Świątko
Certification body

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**
CharDrive handpiece Basic UDI-DI: 59084473NSZ2WL	IIa	NON-STERILE CharDrive handpiece	HD 1023642-1 NB 0197
CharDrive handpiece Basic UDI-DI: 59084473NSZ2.1TJ	IIa	NON-STERILE CharDrive handpiece	HD 1023642-1 NB 0197
CharDrive handpiece Basic UDI-DI: 59084473NSZ2.2TL	IIa	NON-STERILE CharDrive handpiece	HD 1023642-1 NB 0197
NON-STERILE Rod Trial Basic UDI-DI: 59084473NSL1.1QB	IIa	Rod Trial	HD 1023642-1 NB 0197
NON-STERILE Nails Trials Basic UDI-DI: 59084473NSL1.2QD	IIa	Nails Trials Femoral trials Humeral trials Tibial trials	HD 1023642-1 NB 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**
NON-STERILE **Intervertebral cages trials** **Basic UDI-DI: 59084473NSL1.3QF**	IIa	Trials (angular, small, medium, big, etc.)	HD 1023642-1 NB 0197
NON-STERILE **Radial Head Prosthesis Trials** **Basic UDI-DI: 59084473NSL1.4QH**	IIa	RHB head prosthesis trials	HD 1023642-1 NB 0197
NON-STERILE **Plates trials** **Basic UDI-DI: 59084473NSL1.5QK**	IIa	Plates trials	HD 1023642-1 NB 0197
NON-STERILE **Reconstruction plates trials** **Basic UDI-DI: 59084473NSL1.6QM**	IIa	Plates trials	HD 1023642-1 NB 0197
NON-STERILE **Distractor trials** **Basic UDI-DI: 59084473NSL1.7QP**	IIa	Trials	HD 1023642-1 NB 0197
NON-STERILE **Hip prosthesis trials** **Basic UDI-DI: 59084473NSL1.8QR**	IIa	Hip joint endoprosthesis trials	HD 1023642-1 NB 0197
Rotary surgical instruments **Basic UDi-DI: 59084473NL335**	IIa	NON-STERILE Flexible medullary reamers Taps Cutters Drills Countersinks Trephines Guide pins Guide rods Kirschner wires Pins	HD 1023642-1 NB 0197
Tourniquet control unit **Basic UDI-DI: 59084473NZ54K**	IIa	NON-STERILE Single adjustable tourniquet control unit Dual adjustable tourniquet control unit	HD 1023642-1 NB 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**
		EZO-01 electronic single tourniqet control unit EZO-02 electronic dual tourniquet control unit	
Sterile drills **Basic UDI-DI: 59084473SZ65E**	IIa	STERILE Drill bits	HD 1023642-1 NB 0197
Implants for bone fixation: cerclage cable with clamp (STERILE) **Basic UDI-DI: 59084474SP24F**	IIb implantable (WET)	STERILE Wire for cerclage with clamp	HD 1023642-1 NB 0197
Transpalatal distractor **Basic UDI-DI: 59084474NSP1VX**	IIb implantable (WET)	STERILE / NON-STERILE Microplates	HD 1023642-1 NB 0197
Intramedullary nails **Basic UDI-DI: 59084474NSP3.1S2**	IIb implantable (WET)	STERILE / NON-STERILE Compression nails Forearm nails Humeral nails Tibial nails Femoral nails Forearm and clavicle nails Forearm and fibula nails Reconstruction nails Retrograde nails Trochanteric nails Universal nails Anatomical nails Condylar nails Telescopic nails Telescopic nails-sleeves Cancaneal nails Radial nails Intramedullary nails for children Nuts Cancellous screws Compression screws End caps Join trochaneric screws	HD 1023642-1 NB 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
		Locking screws Join perforated screw Fork setting screw Join screws Join telescopic screws Setting screws Join screws (sleeve) Limiter screws Neck screws Spiral screws Locking sets	
Nails for knee joint arthrodesis **Basic UDI-DI:** **59084474NSP3.2S4**	IIb implantable (WET)	STERILE / NON-STERILE CHARFIX2 FN Distances CHARFIX2 FN Nails CHARFIX2 FN Screw T Femoro-tibial nails	HD 1023642-1 NB 0197
Radial nails - SLM **Basic UDI-DI:** **59084474NSP3.3S6**	IIb implantable (WET)	STERILE / NON-STERILE Radial nails	HD 1023642-1 NB 0197
Bone staples **Basic UDI-DI:** **59084474NSP004.1XB**	IIb implantable (WET)	STERILE / NON-STERILE Asymmetrical bone staples Bone staples Oblique bone staples Staples Straight bone staples	HD 1023642-1 NB 0197
Spine stabilization CHARSPINE2 and CHARSPINE2 MIS **Basic UDI-DI:** **59084474NSP5.1SC**	IIb implantable (WET)	STERILE/NON-STERILE Rods Connectors Locking screws Polyaxial screws Monoaxial screws Uniplanar screws Staples	HD 1023642-1 NB 0197
Cervical plates **Basic UDI-DI:** **59084474NSP5.3SG**	IIb implantable (WET)	STERILE/NON-STERILE Cervical plates	HD 1023642-1 NB 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
Craniomaxillofacial plates **Basic UDI-DI: 59084474NSP6.1SH**	IIb implantable (WET)	STERILE/NON-STERILE Microplates Tape Reconstruction plates	HD 1023642-1 NB 0197
Bone plates - upper extermities **Basic UDI-DI: 59084474NSP6.2SK**	IIb implantable (WET)	STERILE/NON-STERILE Locking plates ChLP system Clavicular plate External plates Humerus plates Limited contact plates Compression plates Straight plates: narrow, wide, thin, thick Autocompression plate Small plates Shape plates Microplates Reconstruction plates	HD 1023642-1 NB 0197
Bone plates - pelvis **Basic UDI-DI: 59084474NSP6.3SM**	IIb implantable (WET)	STERILE/NON-STERILE Pubic symphis plates Reconstruction plates Shape plates Locking plates ChLP system Multiplanar plates	HD 1023642-1 NB 0197
Bone plates - lower extermities **Basic UDI-DI: 59084474NSP6.4SP**	IIb implantable (WET)	STERILE/NON-STERILE Locking plates ChLP Angular nails Angular plates Cancaneal plates Shape plates Condyle plates Fibula plates Tibial plates Distance plates Distance plates - wedges External plates	HD 1023642-1 NB 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
		Limited contact plates Compression plates Straight plates: narrow, wide, thin, thick Autocompression plates Osteotomy plates Small plates Tibial condylar plates Trochanteric plates Tubular plates Wedge distance plates	
Thoracic plates **Basic UDI-DI:** **59084474NSP6.5SR**	IIb implantable (WET)	STERILE/NON-STERILE Locking plates ChLP Breastbone plates Stabilizer plates	HD 1023642-1 NB 0197
Sterno-costal plates **Basic UDI-DI:** **59084474NSP6.6ST**	IIb implantable (WET)	STERILE/NON-STERILE Plate-blocker Sterno-costal plates	HD 1023642-1 NB 0197
Growth cartilage locking plates **Basic UDI-DI:** **59084474NSP6.7SV**	IIb implantable (WET)	STERILE/NON-STERILE Locking plates ChLP system HEPI plates	HD 1023642-1 NB 0197
Pediatric bone plates - lower extermities **Basic UDI-DI:** **59084474NSP6.8SX**	IIb implantable (WET)	STERILE/NON-STERILE Locking plates ChLP system	HD 1023642-1 NB 0197
Bone plates - upper extermities – SLM **Basic UDI-DI:** **59084474NSP6.9SZ**	IIb implantable (WET)	STERILE/NON-STERILE Locking plates ChLP system	HD 1023642-1 NB 0197
Bone plates - lower extermities – SLM **Basic UDI-DI:** **59084474NSP6.10UE**	IIb implantable (WET)	STERILE/NON-STERILE Locking plates ChLP	HD 1023642-1 NB 0197
Non-locking bone screws **Basic UDI-DI:** **59084474NSP7.1SN**	IIb implantable (WET)	STERILE/NON-STERILE Compression screws	HD 1023642-1 NB 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
		Compressing screws Cancellous screws Cortical conical screws Cortical screws Cortical self-tapping screws Elbow screws Joint foot screws Knee screws Malleolar screws Navicular screws Navicular self-tapping screws Nuts Pelvic screws Screw-connectors Screws for cortical bone Screws for femur Self-drilling screws Self-tapping screws Sherman screws Microscrews Join cancellous screws Join cannulated screws with collar Join screws Cannulated self-tapping screws Cancellous self-tapping screws External screws Internal screws Screws for small bones Washers Washers 2 holes	
Locking screws (plates) Basic UDI-DI: 59084474NSP7.2SQ	IIb implantable (WET)	STERILE / NON-STERILE Locking screws ChLP system Microscrews Telscopic screws	HD 1023642-1 NB 0197
Locking screws (nails) Basic UDI-DI: 59084474NSP7.3SS	IIb implantable (WET)	STERILE/NON-STERILE Distal screws Proximal screws	HD 1023642-1 NB 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
		Reconstruction screws Locking screws Reconstructive screws	
Locking screws (spine) **Basic UDI-DI:** **59084474NSP7.4SU**	IIb implantable (WET)	STERILE/NON-STERILE Cervical screws Locking screws	HD 1023642-1 NB 0197
Pediatric slipped capital femoral epiphysis screws **Basic UDI-DI:** **59084474NSP7.5SW**	IIb implantable (WET)	STERILE/NON-STERILE Cannulated screws	HD 1023642-1 NB 0197
Subtalar cannulated screws - SLM **Basic UDI-DI:** **59084474NSP7.6SY**	IIb implantable (WET)	STERILE/NON-STERILE Cannulated (subtalar) screws	HD 1023642-1 NB 0197
Subtalar cannulated screws **Basic UDI-DI:** **59084474NSP7.7T2**	IIb implantable (WET)	STERILE/NON-STERILE Cannulated (subtalar) screws	HD 1023642-1 NB 0197
Pins **Basic UDI-DI:** **59084474NP8.1PM**	IIb implantable (WET)	STERILE / NON-STERILE Pins Schanz's screws Screws Steinmann pins Steinmann-Grucy pins Guide rods	HD 1023642-1 NB 0197
Cerclage Wires **Basic UDI-DI:** **59084474NP8.2PP**	IIb implantable (WET)	STERILE / NON-STERILE Wires for cerclage	HD 1023642-1 NB 0197
Femoral bone implants **Basic UDI-DI:** **59084474NSP9.1SY**	IIb implantable (WET)	STERILE/NON-STERILE Dynamic condylar plates DSK Dynamic condylar plates with limited contact DSK Trochanter stabilizing plates Dynamic hip plates DSB	HD 1023642-1 NB 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
		Dynamic hip plates with limited contact DSB Dynamic hip anti-rotary plates Trochanter stabilizing plates	
Implants for ligaments and tendons **Basic UDI-DI:** **59084474NSP10.1TE**	IIb implantable (WET)	STERILE/NON-STERILE Interference screws Interference screws (polymer) Anchoring screws Low profile screws Ligamentous washers Spiked washers Washers with spikes Ligamentous plates	HD 1023642-1 NB 0197
Non-locking nails **Basic UDI-DI:** **59084474NP11.1J5**	IIb implantable (WET)	STERILE / NON-STERILE Rush nails Hackethal-Epibloc nails Kirschner wires	HD 1023642-1 NB 0197
IDS – Inter-Rib Distraction Stabilizer **Basic UDI-DI:** **59084474NP12SQ**	IIb implantable (WET)	NON-STERILE Fixed clamps Sliding clamps Sliding bars Fixed bars Locking clips Locking screws Closing archs Iliac hooks	HD 1023642-1 NB 0197
Femoro-tibial steel nails **Basic UDI-DI:** **59084474NP13SS**	IIb implantable (WET)	NON-STERILE Femoro-tibial nails	HD 1023642-1 NB 0197
Sacroiliac screw **Basic UDI-DI:** **59084474NSP5.2SE**	IIb implantable (WET)	STERILE/NON-STERILE 3D-Ti Sacroiliac screw Washer	HD 1023642-1 NB 0197
Intervertebral cages **Basic UDI-DI:** **59084475NSP2WC**	III	STERILE/NON-STERILE PLIF PEEK cages ALIF PEEK cages TLIF PEEK cages	HD 1023642-1 NB 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
		Cervical cages ALIF PEEK intervertebral locking cage Angular cervical intervertebral locking cage Convex cervical intervertebral locking cage LIF expandable intervertebral cage	
Intervertebral cages – SLM **Basic UDI-DI: 59084475NSP7WN**	III	STERILE 3D-Ti PLIF Intervertebral cages 3D-Ti TLIF Intervertebral cages 3D-Ti PLIF Rotary intervertebral cage 3D-Ti Angular cervical Intervertebral cage 3D-Ti Convex cervical intervertebral cage 3D-Ti Angular cervical intervertebral locking cage 3D-Ti Convex cervical intervertebral locking cage 3D-Ti ALIF intervertebral locking cage 3D-Ti OLIF intervertebral cage 3D-Ti OLIF intervertebral locking cage	HD 1023642-1 NB 0197
Cervical-occipital stabilizator **Basic UDI-DI: 59084475NSP4WG**	III	STERILE / NON-STERILE Occiput plates Occiput screws Rods Connectors Hooks Locking screws Polyaxial screws	HD 1023642-1 NB 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
VBR Prosthesis **Basic UDI-DI:** **59084475NSP3WE**	III	STERILE/NON-STERILE Endplates Mesh body Expanded body Extender	HD 1023642-1 NB 0197
VBR Prosthesis - SLM **Basic UDI-DI:** **59084475NSP8WQ**	III	STERILE/NON-STERILE Endplates Mesh body Expanded body Extender 3D-Ti Expandable body	HD 1023642-1 NB 0197
Spinal hooks **Basic UDI-DI:** **59084475NSP9WS**	III	STERILE/NON-STERILE Hooks Spinal hooks (small, standard, large)	HD 1023642-1 NB 0197
Radial head prosthesis **Basic UDI-DI:** **59084475SP14L**	III	STERILE Stem of radial head prosthesis Angular stem of radial head prosthesis Modular head of radial head prosthesis Solid head of radial head prosthesis	HD 1023642-1 NB 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
Temporomandibular joint implant: ACETABULAR (STERILE) **Basic UDI-DI: N/A**	III custom-made	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
Temporomandibular joint implant: PLATE (NON-STERILE) Basic UDI-DI: N/A	III custom-made	N/A	Notified body involvement not required pursuant to MDD
Talar bone implant (NON-STERILE) Basic UDI-DI: N/A	III custom-made	N/A	Notified body involvement not required pursuant to MDD
Hip joint acetabular cup (STERILE) Basic UDI-DI: N/A	III custom-made	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
2024/05/23	ChM_CL_2023_607_2024-05-23	Initial issue
2024/10/17	ChM_CL_203_607_2024-10-17	List of devices has been updated