

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60144424 0001

**Report No.:** 26300273 015

**Manufacturer:** ChM sp. z o.o.  
Lewickie 3b  
16-061 Juchnowiec Koscielny  
Poland

**Products:** (see attachment for products included)

Replaces EC Certificate, Registration No.: HD 60099942 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2019-11-19

**Date:** 2019-11-19

Notified Body

Rafal Byczkowski



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC  
concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/2, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** HD 60144424 0001  
**Report No.:** 26300273 015

**Manufacturer:** ChM sp. z o.o.  
Lewickie 3b  
16-061 Juchnowiec Koscielny  
Poland

Products included, Class IIb:

- Bone nails (sterile and non-sterile)
- Bone pins (sterile and non-sterile)
- Bone screws (sterile and non-sterile)
- Bone plates (sterile and non-sterile)
- Bone staples (sterile and non-sterile)
- Fixation devices, internal, wire (sterile and non-sterile)
- Fixation devices, internal, spine, construct (sterile and non-sterile)
- Fixation devices, internal, hip, plate, compression (sterile and non-sterile)
- Fixation devices, internal, washer (sterile and non-sterile)
- Radial bone head prosthesis (sterile)
- Dentals implants (sterile)
- Abutments for dental implants (non-sterile)
- Steel surgical sutures (sterile)
- Interference polymer bone screws (sterile and non-sterile)

**Date: 2019-11-19**

**Notified Body**

  
**Rafal Byczkowski**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**


**Registration No.:** HD 60144424 0001  
**Report No.:** 26300273 015

**Manufacturer:** ChM sp. z o.o.  
Lewickie 3b  
16-061 Juchnowiec Koscielny  
Poland

Products included, Class IIa:

- Bone drills (non-sterile)
- Bone cutters (non-sterile)
- Bone reamers (non-sterile)
- Bone tapes (non-sterile)
- Bone countersinks (non-sterile)
- Bone trephines (non-sterile)
- Guide wires for orthopaedic application (non-sterile)
- Trials (non-sterile)
- Cover screws (non-sterile)
- Healing caps (non-sterile)
- Drill bits (sterile)
- Medical drives (non-sterile)
- Tourniquet control units (non-sterile)

**Notified Body**



**Rafal Byczkowski**



**Date: 2019-11-19**

# Certificate



## Quality Management System EN ISO 13485:2016

Registration No.: SX 1023642-1

Organization: ChM sp. z o.o.  
Lewickie 3b  
16-061 Juchnowiec Kościelny  
Poland

Scope: Design and development, manufacture, distribution and service of orthopaedic implants, non-active surgical instruments, medical drives and attachments, tourniquet control units.

Sterilization of medical devices by hydrogen peroxide.

Manufacture of orthopaedic implants using Selective Laser Melting (SLM) technology.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84952558-30  
Effective date: 2021-04-13  
Expiry date: 2024-04-12  
Issue date: 2021-04-08

A blue ink signature is written over a circular stamp. The stamp contains the TÜV Rheinland logo and the text "TÜV Rheinland LGA Products GmbH" and "Zertifizierungsstelle".

Rafał Byczkowski  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



## Declaration of Conformity

**Manufacturer:**

**ChM sp. z o.o.**  
**Lewickie 3b, 16-061 Juchnowiec Kościelny, Poland**

We declare under our sole responsibility that

**medical devices:** Orthopaedic implants  
**models:** Radial bone head prosthesis (sterile)  
**of class:** IIb, rule 8 (main) according to Annex IX of 93/42/EEC Directive  
**covered by:** the Technical File No. CE/IIb-002  
**and:** listed in the annex to this declaration,  
**and for which:** production/releasing documentation (Production Order form) of them is a part of this declaration,

meets intended for these products, all the provisions of 93/42/EEC Directive, as well as Polish Law Regulations: the Medical Devices Act of 20<sup>th</sup> May 2010 (Official Journal of Laws from 2017, item 211), and Regulations of the Polish Minister of Health of 17th February 2016 concerning the essential requirements and conformity assessment procedures for medical devices.

All applicable harmonized standards are listed in above Technical Files.

Conformity assessment procedure: Annex II of 93/42/EEC Directive excepting section 4.

**Notified Body:**

**TÜV Rheinland LGA Products GmbH**  
**Tillystraße 2**  
**D-90431 Nürnberg**



07.02.2018

CE/IIb-002\_Rev: 01\_02/2018\_MD  
Lewickie 3b, 16-061 Juchnowiec Kościelny, Poland

**Andrzej Sobolewski**

**Member of the Board**

name  
position

**ChM** *A. Sobolewski*

Signature  
ChM sp. z o.o.

C Z Ł O N E K | Andrzej  
Z A R Z Ą D U | Sobolewski

**ChM**

ChM sp. z o.o., Lewickie 3b, 16-061 Juchnowiec Kościelny, PL  
tel. +48 85 86 86 100 | c h m @ c h m . e u  
fax +48 85 86 86 101 | w w w . c h m . e u  
NIP 966-11-76-019 | KRS 0000187570

NIP 966-11-76-019

REGON 050561656

Sąd Rejonowy w Białymstoku

XII Wydział Gospodarczy: KRS 0000187570

Wysokość kapitału zakładowego 9 050 000 zł

### Annex to Declaration of Conformity Radial bone head prosthesis (sterile)

REF	NAME OF THE DEVICE
4.3690.000	Stem of radial head prosthesis
4.3691.000	Angular stem of radial head prosthesis
4.3692.010	Modular head of radial head prosthesis 20x10
4.3692.012	Modular head of radial head prosthesis 20x12
4.3692.014	Modular head of radial head prosthesis 20x14
4.3693.010	Modular head of radial head prosthesis 22x10
4.3693.012	Modular head of radial head prosthesis 22x12
4.3693.014	Modular head of radial head prosthesis 22x14
4.3694.010	Modular head of radial head prosthesis 24x10
4.3694.012	Modular head of radial head prosthesis 24x12
4.3694.014	Modular head of radial head prosthesis 24x14
7.3696.010	Solid head of radial head prosthesis 20x10
7.3696.012	Solid head of radial head prosthesis 20x12
7.3696.014	Solid head of radial head prosthesis 20x14
7.3697.010	Solid head of radial head prosthesis 22x10
7.3697.012	Solid head of radial head prosthesis 22x12
7.3697.014	Solid head of radial head prosthesis 22x14
7.3698.010	Solid head of radial head prosthesis 24x10
7.3698.012	Solid head of radial head prosthesis 24x12
7.3698.014	Solid head of radial head prosthesis 24x14

This annex is only valid in connection with the Declaration of Conformity.

07.02.2018

**Andrzej Sobolewski**  
 Member of the Board  
 name  
 position

**ChM**  
 ChM sp. z o.o.  
 Signature  
 CZŁONEK | Andrzej  
 ZARZĄDU | Sobolewski

**ChM**

ChMsp.zo.o., Lewickie3b, 16-061 Juchnowiec Kościelny, PL  
 tel. +48 85 86 86 100 | c h m @ c h m . o o . p l  
 fax +48 85 86 86 101 | w w w . c h m . o o . p l  
 NIP 966-11-76-019 | KRS 0 0 0 0 1 8 7 5 7 0

# CHM<sup>®</sup>

Implanty i narzędzia ortopedyczne

ENDOPROTEZA GŁOWY KOŚCI PROMIENIOWEJ  
RADIAL HEAD PROSTHESIS  
ЭНДОПРОТЕЗ ГОЛОВКИ ЛУЧЕВОЙ КОСТИ



CHM<sup>®</sup>





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Średnica [mm]  
Diameter [mm]  
Диаметр [мм]

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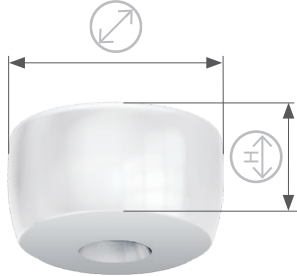




Długość H [mm]  
H length [mm]  
Длина H [мм]

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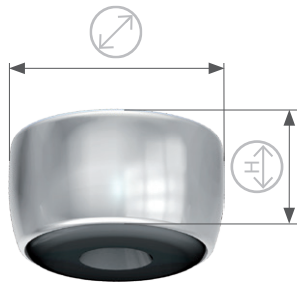
CHM<sup>®</sup>



GŁOWA LITA ENDOPROTEZY GŁOWY KOŚCI PROMIENIOWEJ  
SOLID HEAD OF RADIAL HEAD PROSTHESIS  
СПЛОШНАЯ ГОЛОВКА ЭНДОПРОТЕЗА ГОЛОВКИ ЛУЧЕВОЙ КОСТИ



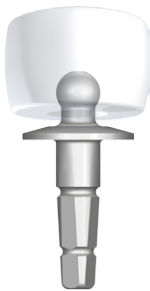
		
	10	7.3696.010
20	12	7.3696.012
	14	7.3696.014
	10	7.3697.010
22	12	7.3697.012
	14	7.3697.014
	10	7.3698.010
24	12	7.3698.012
	14	7.3698.014

GŁOWA MODULARNA ENDOPROTEZY GŁOWY KOŚCI PROMIENIOWEJ  
MODULAR HEAD OF RADIAL HEAD PROSTHESIS  
МОДУЛЬНАЯ ГОЛОВКА ЭНДОПРОТЕЗА ГОЛОВКИ ЛУЧЕВОЙ КОСТИ

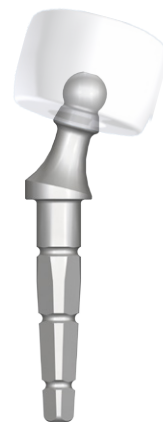







		
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20	12	4.3692.012
	14	4.3692.014
	10	4.3693.010
22	12	4.3693.012
	14	4.3693.014
	10	4.3694.010
24	12	4.3694.012
	14	4.3694.014

TRZPIEŃ ENDOPROTEZY GŁOWY KOŚCI PROMIENIOWEJ  
STEM OF RADIAL HEAD PROSTHESIS  
СТЕРЖЕНЬ ЭНДОПРОТЕЗА ГОЛОВКИ ЛУЧЕВОЙ КОСТИ  
[4.3690.000]



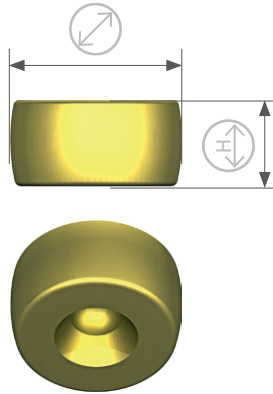
KAŃTOWY TRZPIEŃ ENDOPROTEZY GŁOWY KOŚCI PROMIENIOWEJ  
ANGULAR STEM OF RADIAL HEAD PROSTHESIS  
НОЖКА УГЛОВАЯ ЭНДОПРОТЕЗА ГОЛОВКИ ЛУЧЕВОЙ КОСТИ  
[4.3691.000]





	Nazwa Name Название	Szt. Pcs. Шт.	Nr katalogowy Catalogue no. № по кат.
	Raszpla kości promieniowej Rasp for radial bone Рашпиль для лучевой кости	1	40.5232.000
	Pilnik wygięty prostokątny Rectangular curved file Напильник костный изогнутый, прямоугольный	1	40.5233.000
	Dopychacz trzpienia endoprotezy GKP Rhb prosthesis stem impactor Импактор ножки эндопротеза ГЛК	1	40.5234.000
	Chwytnak trzpienia endoprotezy GKP Rhb prosthesis stem holder Захват стержня эндопротеза ГЛК	1	40.5235.000
	Przymiar głowy kości promieniowej Radial head bone trial Тестовая головка эндопротеза ГЛК	1	40.5236.000

	Nazwa Name Название	Szt. Pcs. Шт.	Nr katalogowy Catalogue no. № по кат.	
	Przymiar głowy endoprotezy GKP 20 H10 Rhb head prosthesis trial 20 H10 Тестовая головка эндопротеза ГЛК 20 H10	1	40.5237.010	
	Przymiar głowy endoprotezy GKP 20 H12 Rhb head prosthesis trial 20 H12 Тестовая головка эндопротеза ГЛК 20 H12	1	40.5237.012	
	Przymiar głowy endoprotezy GKP 20 H14 Rhb head prosthesis trial 20 H14 Тестовая головка эндопротеза ГЛК 20 H14	1	40.5237.014	
	Przymiar głowy endoprotezy GKP 22 H10 Rhb head prosthesis trial 22 H10 Тестовая головка эндопротеза ГЛК 22 H10	1	40.5238.010	
	Przymiar głowy endoprotezy GKP 22 H12 Rhb head prosthesis trial 22 H12 Тестовая головка эндопротеза ГЛК 22 H12	1	40.5238.012	
	Przymiar głowy endoprotezy GKP 22 H14 Rhb head prosthesis trial 22 H14 Тестовая головка эндопротеза ГЛК 22 H14	1	40.5238.014	
	Przymiar głowy endoprotezy GKP 24 H10 Rhb head prosthesis trial 24 H10 Тестовая головка эндопротеза ГЛК 24 H10	1	40.5239.010	
	Przymiar głowy endoprotezy GKP 24 H12 Rhb head prosthesis trial 24 H12 Тестовая головка эндопротеза ГЛК 24 H12	1	40.5239.012	
	Przymiar głowy endoprotezy GKP 24 H14 Rhb head prosthesis trial 24 H14 Тестовая головка эндопротеза ГЛК 24 H14	1	40.5239.014	
		Podstawka przymiarów głów endoprotez Stand for head prosthesis trials Подставка для образцовых мер головок эндопротез	1	40.5240.000
		Prowadnica do resekcji 10 Resection guide 10 Направитель для резекции 10	1	40.5242.010
		Prowadnica do resekcji 12 Resection guide 12 Направитель для резекции 12	1	40.5242.012
Prowadnica do resekcji 14 Resection guide 14 Направитель для резекции 14		1	40.5242.014	
	Pokrywa aluminiowa perfor. 1/2 306x272x15mm Szara Perforated aluminum lid 1/2 306x272x15mm gray Перфорир.алюм.покрышка 1/2 306x272x15мм Серая	1	12.0751.200	
	Wkładka statywu do endoprotez GKP Stand insert rhb prosthesis Вкладыш для подставки для эндопротезов глк	1	40.5249.100	
	Kontener z litym dnem 1/2 306x272x85mm Container with solid bottom 1/2 306x272x85mm Контейнер со сплошным дном 1/2 306x272x85мм	1	12.0751.100	

PRZYMIAR GŁOWY ENDOPROTEZY GKP  
RHB HEAD PROsthESIS TRIAL  
ТЕСТОВАЯ ГОЛОВКА ЭНДОПРОТЕЗА ГЛК




			
	10		40.5237.010
20	12		40.5237.012
	14		40.5237.014
22	10		40.5238.010
	12		40.5238.012
	14		40.5238.014
24	10		40.5239.010
	12		40.5239.012
	14		40.5239.014

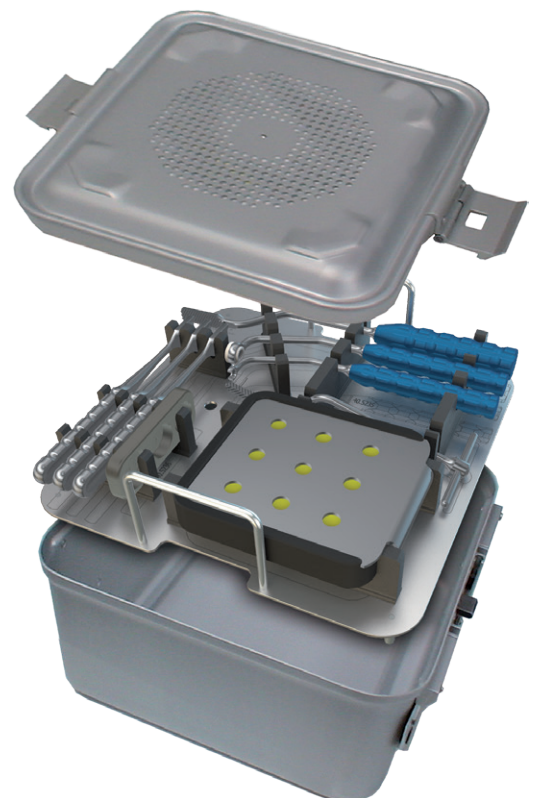
PROWADNICA DO RESEKCJI (W PRZYPADKU UŻYCIA TRZPIENIA [4.3690.000])  
RESECTION GUIDE (IN THE CASE OF USING THE STEM [4.3690.000])  
НАПРАВИТЕЛЬ ДЛЯ РЕЗЕКЦИИ (В СЛУЧАЕ ПРИМЕНЕНИЯ НОЖКИ [4.3690.000])



Głowa lita endoprotezy głowy  
kości promieniowej  
Solid head of radial head  
prosthesis  
Сплошная головка эндопротеза  
головки лучевой кости

		
	10	40.5242.010
	12	40.5242.012
	14	40.5242.014

INSTRUMENTARIUM DO ENDOPROTEZ GKP INSTRUMENTS FOR RADIAL  
HEAD PROsthESIS INSTRUMENTARIUM ДЛЯ ЭНДОПРОТЕЗА ГОЛОВКИ  
ЛУЧЕВОЙ КОСТИ  
[40.5231.000]



CHM<sup>®</sup>

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