

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices
for the following scope

(see attachment for scope)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-04-13
Certificate Registration No.: SX 60128456 0001
An audit was performed. Report No.: 26300273 009
This Certificate is valid until: 2021-04-12

Certification Body



Date 2018-04-13



M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate
Registration No.:**
Report No.:

SX 60128456 0001
26300273 009

Organization:

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

Scope:

Design and development, manufacture and distribution of

- Orthopaedic implants
- Dental implants with accessories
- Steel surgical sutures
- Non-active surgical instruments
- Medical drives and attachments
- Tourniquet control units

Sterilization of medical devices by hydrogen peroxide

Certification Body



Date: 2018-04-13

M. Aihara
M.Sc. M. Aihara

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

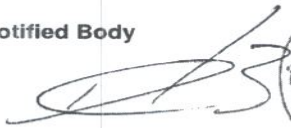
Expiry Date: 2024-05-26

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

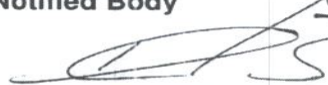
Manufacturer: ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Koscielny
Poland

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)

Notified Body

Date: 2019-11-19


Rafal Byczkowski



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

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

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

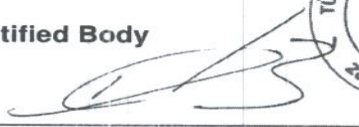
Manufacturer: ChM sp. z o.o.
Lewickie 3b
16-061 Juchnowiec Koscielny
Poland

Products included, Class 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)

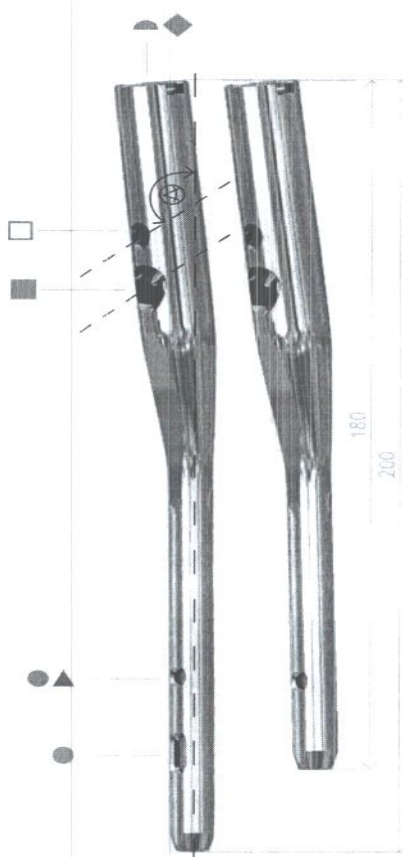
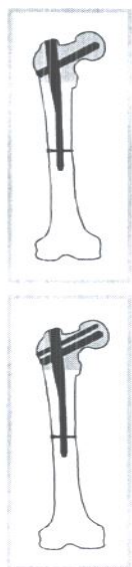
Date: 2019-11-19

Notified Body


Rafal Byczkowski



Charfix Femoral Nail
ChFN system



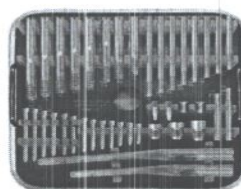
		len	
130°	10	180	3.4876.180
		200	3.4876.200
	11	180	3.4877.180
		200	3.4877.200
130° Recommended	12	180	3.4878.180
		200	3.4878.200

available  Ø 10 mm - 12 mm 1 mm
L 180 mm - 240 mm pitch 5 mm

	3.1938.xxx	✓	11	70÷120	■
	3.2104.003	✓			□
	3.1935.xxx	✓	6.5	70÷120	▲
	3.1657.xxx	✓	5.0	30÷60	●
	3.1654.xxx	✓	4.5	30÷60	◆
	3.2106.008	✓			
	3.2104.6xx	✓		0÷15	

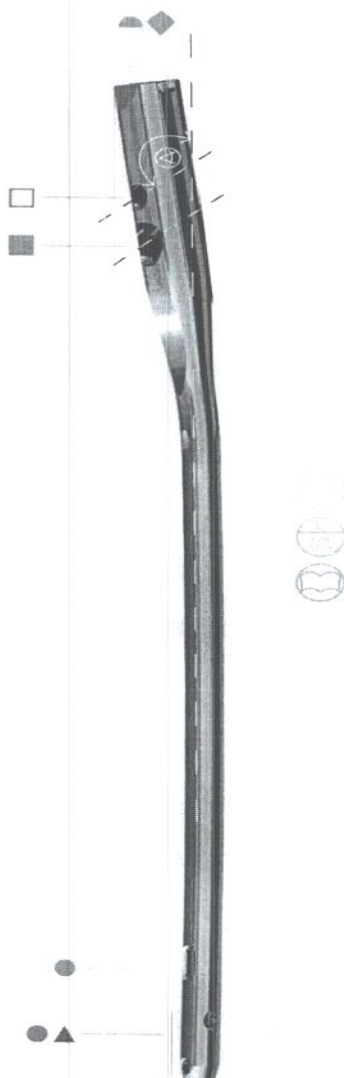
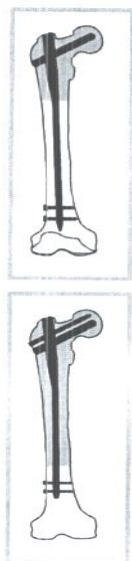
Charfis Femoral Nail
ChFN *system*

				
125°	10	180	3.4864.180	
		200	3.4864.200	
	11	180	3.4865.180	
		200	3.4865.200	
135°	12	180	3.4866.180	
		200	3.4866.200	
	10	180	3.4888.180	
		200	3.4888.200	
	11	180	3.4889.180	
		200	3.4889.200	
	12	180	3.4890.180	
		200	3.4890.200	
available		Ø	10 mm + 12 mm	
		L	180 mm + 240 mm	
			pitch	1 mm
				5 mm



Stand for ChFN trochanteric nails (set with a box without implants)

40.4687.200

Charfix Femoral Nail
ChFN system

		1 en		
10	340	3.4951.340	3.4950.340	
	360	3.4951.360	3.4950.360	
	380	3.4951.380	3.4950.380	
	400	3.4951.400	3.4950.400	
11	420	3.4951.420	3.4950.420	
	340	3.4953.340	3.4952.340	
	360	3.4953.360	3.4952.360	
	380	3.4953.380	3.4952.380	
12	400	3.4953.400	3.4952.400	
	420	3.4953.420	3.4952.420	
	340	3.4955.340	3.4954.340	
	360	3.4955.360	3.4954.360	
	380	3.4955.380	3.4954.380	
	400	3.4955.400	3.4954.400	
	420	3.4955.420	3.4954.420	

130° Recommended

available	Ø	10 mm - 12 mm	pitch	1 mm
	L	280 mm - 480 mm		5 mm



3.1938.xxx	✓	✓	11	70÷120	■
3.2104.003	✓	✓			
3.1935.xxx	✓	✓	6.5	70÷120	□
3.1657.xxx	✓	✓	5.0	30÷80	▲
3.1654.xxx	✓		4.5	30÷80	●
3.2106.008	✓				◐
3.2104.6xx	✓	✓	0÷15		◆

Charfix Femoral Nail
ChFN system

					
					
					
					
					
10		340	3.4927.340	3.4926.340	
		360	3.4927.360	3.4926.360	
		380	3.4927.380	3.4926.380	
		400	3.4927.400	3.4926.400	
		420	3.4927.420	3.4926.420	
125°	11	340	3.4929.340	3.4928.340	
		360	3.4929.360	3.4928.360	
		380	3.4929.380	3.4928.380	
		400	3.4929.400	3.4928.400	
		420	3.4929.420	3.4928.420	
12	12	340	3.4931.340	3.4930.340	
		360	3.4931.360	3.4930.360	
		380	3.4931.380	3.4930.380	
		400	3.4931.400	3.4930.400	
		420	3.4931.420	3.4930.420	
10	10	340	3.4975.340	3.4974.340	
		360	3.4975.360	3.4974.360	
		380	3.4975.380	3.4974.380	
		400	3.4975.400	3.4974.400	
		420	3.4975.420	3.4974.420	
135°	11	340	3.4977.340	3.4976.340	
		360	3.4977.360	3.4976.360	
		380	3.4977.380	3.4976.380	
		400	3.4977.400	3.4976.400	
		420	3.4977.420	3.4976.420	
12	12	340	3.4979.340	3.4978.340	
		360	3.4979.360	3.4978.360	
		380	3.4979.380	3.4978.380	
		400	3.4979.400	3.4978.400	
		420	3.4979.420	3.4978.420	

available



Ø

10 mm - 12 mm

pitch

5 mm

L

280 mm - 480 mm



CHARFIX DISTAL SCREW 4.5



30	3.1654.030
35	3.1654.035
40	3.1654.040
45	3.1654.045
50	3.1654.050
55	3.1654.055
60	3.1654.060
65	3.1654.065
70	3.1654.070
75	3.1654.075
80	3.1654.080



CHARFIX DISTAL SCREW 5.0



30	3.1657.030
35	3.1657.035
40	3.1657.040
45	3.1657.045
50	3.1657.050
55	3.1657.055
60	3.1657.060
65	3.1657.065
70	3.1657.070
75	3.1657.075
80	3.1657.080



ChFN JOIN CANNULATED TROCHANTERIC SCREW WITH COLLAR 6.5



70	3.1935.070
75	3.1935.075
80	3.1935.080
85	3.1935.085
90	3.1935.090
95	3.1935.095
100	3.1935.100
105	3.1935.105
110	3.1935.110
115	3.1935.115
120	3.1935.120

ChFN JOIN CANNULATED TROCHANTERIC SCREW WITH COLLAR 11



70	3.1938.070
75	3.1938.075
80	3.1938.080
85	3.1938.085
90	3.1938.090
95	3.1938.095
100	3.1938.100
105	3.1938.105
110	3.1938.110
115	3.1938.115
120	3.1938.120



ChFN END CAP M12X1.75



A	
0	3.2104.600
+5	3.2104.605
+10	3.2104.610
+15	3.2104.615

ChFN END CAP M8X1.25



3.2104.003

ChFN COMPRESSION SCREW M8X1.25



3.2106.008

Charfix Femoral Nail
ChFN system
CHARFIX system



40.5520.600

Name

Pcs.

Catalogue no.



Targeter arm

1

40.5541.000



Targeter 120/130

1

40.5542.100



Targeter 125/135

1

40.5543.100



Distal targeter D

1

40.5546.000



Drill guide 14/12

1

40.5544.100



Protective guide 12/2.8

1

40.5545.100



Connecting screw M12x1.75 L-34

1

40.5547.000



Drill guide 9.0/7.0

1

40.5537.100



Protective guide 7.0/2.8

1

40.5538.100



Drill with scale 3.5/350

2

40.5339.001



Drill guide 7/3.5

2

40.5511.100



Protective guide 9/7

2

40.5510.100



Compression wrench

1

40.5532.300



Screwdriver S3.5

1

40.5525.100



Cannulated screwdriver S4

1

40.5524.300



Drill 6.5

1

40.5529.000



Gradual drill 11/6.5

1

40.5528.000



40.5520.600

	Name	Pcs.	Catalogue no.
	Screwdriver S10	1	40.5521.000
	Mallet	1	40.3667.000
	Wrench S10	1	40.5526.100
	Impactor-extractor	1	40.5507.000
	Curved awl 8.0	1	40.5523.000
	Protective guide 20.0/17.0	1	40.4711.000
	Guide 17.0/2.8	1	40.4712.100
	Set block 9/4.5	2	40.5533.000
	Cannulated drill 17.0	1	40.4715.000
	Connector of extractor M12x1.75	1	40.4731.000
	Trocar 2.8	1	40.5527.000
	Trocar 6.5	1	40.5534.000
	Screw length measure	1	40.5530.000
	Cannulated screw length measure	1	40.4724.000
	Nail length measure	1	40.4798.500
	Teflon pipe guide	1	40.1348.000
	Guide rod 3.0/580	1	40.3925.580
	Guide rod 2.8/385	4	40.5531.000

Chardix Femoral Nail
ChFN system

40.5520.600

Name

Pcs.

Catalogue no.



Steinmann handle

1

40.0987.200



Wrench for self-aligning joint S4

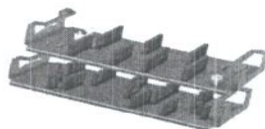
1

40.5540.000

Perforated aluminum cover
1/1 595x275x15mm gray

1

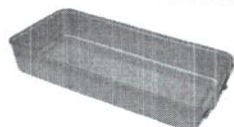
12.0750.200



Stand f/instr.set of ChFN trochanteric nails

1

40.5549.600

Container with solid bottom 1/1
595x275x185mm

1

12.0750.103