



# CERTIFICATE

**EC Certificate No. 1434-MDD-346/2021**  
**Full Quality Assurance System**  
**Directive 93/42/EEC concerning medical devices**

Polish Centre for Testing and Certification certifies  
that the quality assurance system in the organization:

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

for the design, manufacture and final inspection of  
medical devices, class III

## **HIP JOINT ENDOPROSTHESIS**

*The list of medical devices covered by this certificate is provided in the Annexes 1-3 to EC Design-examination Certificate No. 1434-MDD-345/2021*

complies with requirements  
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)  
implemented into Polish law,  
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 24.05.2021 to 27.05.2024

The date of issue of the Certificate: 24.05.2021

The date of the first issue of the Certificate: 24.05.2021



Issued under the Contract No. **MD-133/2020**  
Application No: 144/2020  
Certificate bears the qualified signature.  
Warsaw, 24/05/2021  
Module H2/3/4/5

Anna  
Małgorzata  
Wyroba

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.05.24  
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**Vice-President**



# CERTIFICATE

**EC Certificate No. 1434-MDD-345/2021**  
**EC Design-examination**  
**Directive 93/42/EEC concerning medical devices**

Polish Centre for Testing and Certification certifies  
that the documentation submitted by:

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

related to the medical device, class III

**HIP JOINT ENDOPROSTHESIS**

*The list of medical devices covered by this certificate is provided in the Annexes 1-3*

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 24.05.2021 to 27.05.2024

The date of issue of the Certificate: 24.05.2021

The date of the first issue of the Certificate: 24.05.2021



Issued under the Contract No. **MD-133/2020**  
Application No: **144/2020**  
Certificate bears the qualified signature.  
Warsaw, 24/05/2021  
Module **H1**

Anna  
Małgorzata  
Wyroba

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.05.24  
12:16:19 +02'00'

**Vice-President**



# ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-MDD-345/2021**

*List of medical devices covered by the certificate:*

REF	Medical device name
3.3601.008S	Cementless stem 8 STANDARD
3.3601.009S	Cementless stem 9 STANDARD
3.3601.010S	Cementless stem 10 STANDARD
3.3601.011S	Cementless stem 11 STANDARD
3.3601.012S	Cementless stem 12 STANDARD
3.3601.013S	Cementless stem 13 STANDARD
3.3601.014S	Cementless stem 14 STANDARD
3.3601.015S	Cementless stem 15 STANDARD
3.3601.016S	Cementless stem 16 STANDARD
3.3601.017S	Cementless stem 17 STANDARD
3.3601.018S	Cementless stem 18 STANDARD
REF	Medical device name
3.3630.044S	Acetabular shell 44 3hol.
3.3630.046S	Acetabular shell 46 3hol.
3.3630.048S	Acetabular shell 48 3hol.
3.3630.050S	Acetabular shell 50 3hol.
3.3630.052S	Acetabular shell 52 3hol.
3.3630.054S	Acetabular shell 54 3hol.
3.3630.056S	Acetabular shell 56 3hol.
3.3630.058S	Acetabular shell 58 3hol.
3.3630.060S	Acetabular shell 60 3hol.
3.3630.062S	Acetabular shell 62 3hol.
3.3630.064S	Acetabular shell 64 3hol.
3.3630.066S	Acetabular shell 66 3hol.
3.3630.068S	Acetabular shell 68 3hol.
3.3631.044S	Acetabular shell 44 solid
3.3631.046S	Acetabular shell 46 solid
3.3631.048S	Acetabular shell 48 solid
3.3631.050S	Acetabular shell 50 solid
3.3631.052S	Acetabular shell 52 solid
3.3631.054S	Acetabular shell 54 solid
3.3631.056S	Acetabular shell 56 solid
3.3631.058S	Acetabular shell 58 solid
3.3631.060S	Acetabular shell 60 solid
3.3631.062S	Acetabular shell 62 solid
3.3631.064S	Acetabular shell 64 solid
3.3631.066S	Acetabular shell 66 solid
3.3631.068S	Acetabular shell 68 solid



Issued under the Contract No. **MD-133/2020**  
Application No: **144/2020**  
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Warsaw, 24/05/2021

Anna  
Małgorzata  
Wyroba  
Vice-President

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.05.24  
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## ANNEX 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-MDD-345/2021**

*List of medical devices covered by the certificate:*

REF	Medical device name
4.0028.001S	Head 28S
4.0028.002S	Head 28M
4.0028.003S	Head 28L
4.0032.001S	Head 32S
4.0032.002S	Head 32M
4.0032.003S	Head 32L
4.0036.001S	Head 36S
4.0036.002S	Head 36M
4.0036.003S	Head 36L
REF	Medical device name
7.3635.044S	Acetabular liner 28/44 STANDARD
7.3635.046S	Acetabular liner 28/46 STANDARD
7.3635.048S	Acetabular liner 28/48 STANDARD
7.3635.050S	Acetabular liner 28/50 STANDARD
7.3635.052S	Acetabular liner 28/52 STANDARD
7.3635.054S	Acetabular liner 28/54 STANDARD
7.3635.056S	Acetabular liner 28/56 STANDARD
7.3635.058S	Acetabular liner 28/58 STANDARD
7.3635.060S	Acetabular liner 28/60 STANDARD
7.3635.062S	Acetabular liner 28/62 STANDARD
7.3635.064S	Acetabular liner 28/64 STANDARD
7.3635.066S	Acetabular liner 28/66 STANDARD
7.3635.068S	Acetabular liner 28/68 STANDARD
7.3636.048S	Acetabular liner 32/48 STANDARD
7.3636.050S	Acetabular liner 32/50 STANDARD
7.3636.052S	Acetabular liner 32/52 STANDARD
7.3636.054S	Acetabular liner 32/54 STANDARD
7.3636.056S	Acetabular liner 32/56 STANDARD
7.3636.058S	Acetabular liner 32/58 STANDARD
7.3636.060S	Acetabular liner 32/60 STANDARD
7.3636.062S	Acetabular liner 32/62 STANDARD
7.3636.064S	Acetabular liner 32/64 STANDARD
7.3636.066S	Acetabular liner 32/66 STANDARD
7.3636.068S	Acetabular liner 32/68 STANDARD
7.3637.052S	Acetabular liner 36/52 STANDARD
7.3637.054S	Acetabular liner 36/54 STANDARD
7.3637.056S	Acetabular liner 36/56 STANDARD
7.3637.058S	Acetabular liner 36/58 STANDARD
7.3637.060S	Acetabular liner 36/60 STANDARD
7.3637.062S	Acetabular liner 36/62 STANDARD
7.3637.064S	Acetabular liner 36/64 STANDARD
7.3637.066S	Acetabular liner 36/66 STANDARD
7.3637.068S	Acetabular liner 36/68 STANDARD



Issued under the Contract No. **MD-133/2020**

Application No: **144/2020**

Certificate bears the qualified signature.

Warsaw, 24/05/2021

Anna  
Małgorzata  
Wyroba

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.05.24  
12:18:33 +02'00'  
**Vice-President**



# ANNEX 3 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-MDD-345/2021**

*List of medical devices covered by the certificate:*

REF	Medical device name
7.3639.044S	Acetabular liner 28/44 HIGH WALL
7.3639.046S	Acetabular liner 28/46 HIGH WALL
7.3639.048S	Acetabular liner 28/48 HIGH WALL
7.3639.050S	Acetabular liner 28/50 HIGH WALL
7.3639.052S	Acetabular liner 28/52 HIGH WALL
7.3639.054S	Acetabular liner 28/54 HIGH WALL
7.3639.056S	Acetabular liner 28/56 HIGH WALL
7.3639.058S	Acetabular liner 28/58 HIGH WALL
7.3639.060S	Acetabular liner 28/60 HIGH WALL
7.3639.062S	Acetabular liner 28/62 HIGH WALL
7.3639.064S	Acetabular liner 28/64 HIGH WALL
7.3639.066S	Acetabular liner 28/66 HIGH WALL
7.3639.068S	Acetabular liner 28/68 HIGH WALL
7.3640.048S	Acetabular liner 32/48 HIGH WALL
7.3640.050S	Acetabular liner 32/50 HIGH WALL
7.3640.052S	Acetabular liner 32/52 HIGH WALL
7.3640.054S	Acetabular liner 32/54 HIGH WALL
7.3640.056S	Acetabular liner 32/56 HIGH WALL
7.3640.058S	Acetabular liner 32/58 HIGH WALL
7.3640.060S	Acetabular liner 32/60 HIGH WALL
7.3640.062S	Acetabular liner 32/62 HIGH WALL
7.3640.064S	Acetabular liner 32/64 HIGH WALL
7.3640.066S	Acetabular liner 32/66 HIGH WALL
7.3640.068S	Acetabular liner 32/68 HIGH WALL
7.3641.052S	Acetabular liner 36/52 HIGH WALL
7.3641.054S	Acetabular liner 36/54 HIGH WALL
7.3641.056S	Acetabular liner 36/56 HIGH WALL
7.3641.058S	Acetabular liner 36/58 HIGH WALL
7.3641.060S	Acetabular liner 36/60 HIGH WALL
7.3641.062S	Acetabular liner 36/62 HIGH WALL
7.3641.064S	Acetabular liner 36/64 HIGH WALL
7.3641.066S	Acetabular liner 36/66 HIGH WALL
7.3641.068S	Acetabular liner 36/68 HIGH WALL
REF	Medical device name
9.0028.001S	Head 28 S
9.0028.002S	Head 28 M
9.0028.003S	Head 28 L
9.0032.001S	Head 32 S
9.0032.002S	Head 32 M
9.0032.003S	Head 32 L
9.0036.001S	Head 36 S
9.0036.002S	Head 36 M
9.0036.003S	Head 36 L



Issued under the Contract No. **MD-133/2020**  
Application No: **144/2020**  
Certificate bears the qualified signature.  
Warsaw, 24/05/2021

Anna  
Małgorzata  
Wyroba  
Vice-President

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.05.24  
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