# EU Technical Documentation Assessment Certificate

We hereby certify that the company

**Falcon Medical Medizinische Spezialprodukte GmbH**
**Meiereigasse 2**
**2340 Mödling**
**Austria**

has submitted a technical documentation in accordance with Annexes II and III of Regulation (EU) 2017/745, which meets the following requirements:

## Annex IX – Chapter II (Assessment of the Technical Documentation)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 4 pages. Details of the devices covered as well as further information and conditions are contained on the following pages.

| | | | |
|---|---|---|---|
| Valid from | 2024-08-26 | Registration No. | D4007300011 |
| Valid until | 2029-08-25 | Report No. | P22-00953-239303 |

Stuttgart, 2024-08-26

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-098

## Devices:

Monocon, Monocon MIS, MiniMIS, Monocon Revision Stem
Monocon Stem N 01
Monocon Stem N 02
Monocon Stem N 03
Monocon Stem N 04
Monocon Stem N 05
Monocon Stem N 06
Monocon Stem N 07
Monocon Stem N 08
Monocon Stem N 09
Monocon Stem N 10
Monocon Stem N 11
Monocon Stem N 12
Monocon Stem L 01
Monocon Stem L 02
Monocon Stem L 03
Monocon Stem L 04
Monocon Stem L 05
Monocon Stem L 06
Monocon Stem L 07
Monocon Stem L 08
Monocon Stem L 09
Monocon Stem L 10
Monocon Stem SL 01
Monocon Stem SL 02
Monocon Stem SL 03
Monocon Stem SL 04
Monocon Stem SL 05
Monocon Stem SL 06
Monocon Stem SL 07
Monocon Stem SL 08
Monocon Stem SL 09
Monocon Stem SL 10
Monocon Stem NL 01
Monocon Stem NL 02
Monocon Stem NL 03
Monocon Stem NL 04
Monocon Stem NL 05
Monocon Stem NL 06
Monocon Stem NL 07
Monocon Stem NL 08
Monocon Stem NL 09
Monocon Stem NL 10
Monocon MIS Stem N 01
Monocon MIS Stem N 02

Monocon MIS Stem N 03
Monocon MIS Stem N 04
Monocon MIS Stem N 05
Monocon MIS Stem N 06
Monocon MIS Stem N 07
Monocon MIS Stem N 08
Monocon MIS Stem N 09
Monocon MIS Stem N 10
Monocon MIS Stem N 11
Monocon MIS Stem N 12
Monocon MIS Stem NL 01
Monocon MIS Stem NL 02
Monocon MIS Stem NL 03
Monocon MIS Stem NL 04
Monocon MIS Stem NL 05
Monocon MIS Stem NL 06
Monocon MIS Stem NL 07
Monocon MIS Stem NL 08
Monocon MIS Stem NL 09
Monocon MIS Stem NL 10
Monocon MIS Stem NL 11
Monocon MIS Stem NL 12
MiniMIS Stem N 01
MiniMIS Stem N 02
MiniMIS Stem N 03
MiniMIS Stem N 04
MiniMIS Stem N 05
MiniMIS Stem N 06
MiniMIS Stem N 07
MiniMIS Stem N 08
MiniMIS Stem N 09
MiniMIS Stem N 10
MiniMIS Stem N 11
MiniMIS Stem NL 03
MiniMIS Stem NL 04
MiniMIS Stem NL 05
MiniMIS Stem NL 06
MiniMIS Stem NL 07
MiniMIS Stem NL 08
MiniMIS Stem NL 09
MiniMIS Stem NL 10
MiniMIS Stem NL 11
MiniMIS Stem SL 03
MiniMIS Stem SL 04
MiniMIS Stem SL 05
MiniMIS Stem SL 06
MiniMIS Stem SL 07
MiniMIS Stem SL 08
MiniMIS Stem SL 09
MiniMIS Stem SL 10
MiniMIS Stem SL 11

Monocon Revision Stem N 02
Monocon Revision Stem N 03
Monocon Revision Stem N 04
Monocon Revision Stem N 05
Monocon Revision Stem N 06
Monocon Revision Stem N 07
Monocon Revision Stem N 08
Monocon Revision Stem N 09
Monocon Revision Stem N 10
Monocon Revision Stem N 11
Monocon Revision Stem N 12
Monocon Revision Stem NL 02
Monocon Revision Stem NL 03
Monocon Revision Stem NL 04
Monocon Revision Stem NL 05
Monocon Revision Stem NL 06
Monocon Revision Stem NL 07
Monocon Revision Stem NL 08
Monocon Revision Stem NL 09
Monocon Revision Stem NL 10
Monocon Revision Stem NL 11
Monocon Revision Stem NL 12

Intended purpose:
Replacement of a human hip joint in adults (completed bone growth) following medical indication for restoration of mobility and alleviation of pain by implanting a stem with a head (metal or ceramic) and an acetabular implant with a corresponding insert or a dual head or hemi-head in a natural acetabulum by means of an invasive (surgical) procedure performed by trained personnel (orthopaedic or trauma surgeon) using specific shaping rasps/cutters to achieve high primary stability and secondary lasting integration into the bone via growth on the surface of the implant.

Risk class: III
Basic UDI-DI: 9010030-10-01-10000101TB

## Notes:

For the placing on the market of the devices an EU Quality Management System Certificate according to Annex IX, Chapter I of Regulation (EU) 2017/745 on medical devices is also required.