# EU Quality Management System Certificate

| Certificate no. | Final Assessment Report no. | Effective date | Expiry date |
|---|---|---|---|
| 7512GB448240314 | 7512AU05F | 2024-03-14 | 2026-11-24 |

This is to certify that the quality system of

## Baat Medical Products B.V.

F. Hazemeijerstraat 800, 7555 RJ Hengelo, Overijssel, The Netherlands

SRN: NL-MF-000001569

For design, production, and final product inspection/testing of

**Medical devices/groups of medical devices listed on the following pages**

Has been assessed and found to comply with respect to

**The conformity assessment procedure described in Annex IX, Chapters I and III of Regulation (EU) 2017/745 on Medical Devices**

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
**Hamburg, 2024-03-14**

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
**DNV MEDCERT GmbH – Notified Body 0482**
**Pilatuspool 2, 20355 Hamburg, Germany**

**Lorenz Runge**
Director Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com

Certificate no.: 7512GB448240314
Place and date: Hamburg, 2024-03-14

## Preceding certificate

| Certificate no. | Issue date | Identification of changes |
|---|---|---|
| 7512GB448231206 | 2023-12-06 | Addition of Class IIa nd Class IIb devices |

## Sites covered by this certificate

Baat Medical Products B.V., F. Hazemeijerstraat 800, 7555 RJ Hengelo, Overijssel, The Netherlands

## Products covered by this certificate

### Class I medical devices

For class I medical devices that are reusable surgical instruments (class Ir), the audit of the quality management system was limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, and the related instructions for use.

| Category | Class | Medical devices/groups of medical devices |
|---|---|---|
| MDN 1208 | Ir | Non-active non-implantable instruments |

### Class IIa medical devices

| Category | EMDN code | Medical devices/groups of medical devices |
|---|---|---|
| MDN 1208 | L0910 | Osteosynthesis instruments, reusable |

### Class IIb medical devices, excluding implantable non-WET*

| Category | EMDN code | Medical devices/groups of medical devices |
|---|---|---|
| MDN 1102 | P09120299 | Osteosynthesis nails - other |

**Intended purpose**

The intended purpose of the product is to treat stable extracapsular intertrochanteric (pertrochanteric) femur fractures and intracapsular femoral neck fractures

| Category | EMDN code | Medical devices/groups of medical devices |
|---|---|---|
| MDN 1102 | P090999 | Knee prostheses - other |

**Intended purpose**

The OFP is intended to provide a fixed support for the connection of an artificial limb prosthesis to the residual femoral bone after transfemoral amputation, in all those cases of complications after, or contraindications to the use of conventional socket connections. The OTNi Osseointegrated Femoral Prosthesis provides a bone anchorage point, to support the bone in cases of treatment of traumatic injuries or in corrective surgery, when the knee joint is replaced by an exoprosthesis because of an above-knee amputation. The OFP is a non-active surgical implant designed for long-term implantation inside the human body. It is intended to be used by (orthopaedic-) surgeons with good knowledge of the specific operative technique, in a standard orthopaedic environment, for skeletally mature patients.

* WET (well-established technology) devices are those exempted according to Article 52 (4 and 5) from the requirement of assessment of technical documentation for every device, e.g. sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors.