



# EU Quality Management Certificate



This is to certify that the company

## S.H.Pitkar Orthotools Pvt. Ltd.

RMK Industries Park II, Gat no. 36 & 37  
Jadhavwadi, Navlakh Umbare, Taluka- Maval  
Pune 410507  
India

SRN: IN-MF-000028708

has established, implemented and maintains a Quality Management System in accordance with

### **Annex IX, Chapter I and III of the Regulation (EU) 2017/745 Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.  
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	550821 MDR2017Q
Certificate ID	1000225567
Effective date	2026-01-29
Expiry date	2031-01-28
Frankfurt am Main,	2026-01-29



## DQS Medizinprodukte GmbH

Heinrich von Mettenheim  
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main  
**DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.**  
The validity of the certification can only be verified by the QR-code.



**Annex to EU Quality Management Certificate**  
**SRN of Manufacturer: IN-MF-000028708**  
**Certificate ID: 1000225567**

**Authorised Representative of the company:**

**Obelis S.A.**

Bd. General Wahis 53  
1030 Brussels  
Belgium

SRN: BE-AR-000000106

**Device categories and variants covered by this certificate:**

Device category: **MDN 1102/A - Non-active rigid osteo- and orthopaedic implants**  
Product name: Bone Plate Trauma Fixation System  
Risk classification: IIb implant  
Basic-UDI-DI: 0890426208872G6  
Intended purpose: The bone plates are intended for internal fixation of fractures and reconstruction of bones including the Scapula, Olecranon, Humerus, Radius, Ulna, Pelvis, Distal, Tibia, Fibula, Hand and Foot in adults and for long bones in adolescents in whom the growth plates are fused.

Device category: **MDN 1102/A - Non-active rigid osteo- and orthopaedic implants**  
Product name: Bone Screw Trauma Fixation System  
Risk classification: IIb implant  
Basic-UDI-DI: 0890426208871G4  
Intended purpose: Bone Screws are intended for internal fixation of fractures and reconstruction of bones including the Humerus, Tibia, Fibula, Hand and Foot in adults and for long bones in adolescents.

**Examinations and tests performed:**

550821\_A212821MED dated 2024-04-22  
550821\_A211548MED Bone Plate Trauma Fixation System dated 2025-04-14  
550821\_A211550MED Bone Screw Trauma Fixation System dated 2025-11-06

**Further conditions for or limitations to the validity of the certificate:**

n/a

**Reference to previous certificates:**

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a