EU Quality Management Certificate

This is to certify that the company

Osstell AB

Stampgatan 14
41101 Göteborg
Sweden

SRN: SE-MF-000002162

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.	543847 MDR2017Q
Certificate ID	1000236947
Effective date	2025-06-12
Expiry date	2027-01-05
Frankfurt am Main,	2025-06-12

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

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.

420.90 Version 7.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: SE-MF-000002162
Certificate ID: 1000236947

Device categories and variants covered by this certificate:

Device category:	**MDN 1214-2 - General non-active non-implantable devices used in health care and other non-active non-implantable devices / Dental technology**
Product name:	SmartPeg
Risk classification:	Is
Basic-UDI-DI:	9010522SmartPegsBP
Intended purpose:	Intended to be used as an accessory to Osstell instruments for measuring implant stability.

Examinations and tests performed:
543847_208506_Osstell_420_11e_Report_MEDMDR20211108 dated 2021-12-22
543847_A208506MED_01 MDR TD Product Beacon+ dated 2021-10-08
Report_TechnicalFileReviewOsstellSmartPagV4 dated 2021-11- 19

Further conditions for or limitations to the validity of the certificate:
In case of products that are placed on the market in sterile condition, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects of manufacture concerned with securing and maintaining sterile condition.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2022-01-06	170779326	Addition of the product SmartPeg Type 98 Neoss MUA
02	2024-02-21	170781597	Addition of SmartPeg Type 117
03	2024-05-02	1000177572	Reclassifying of the products 103000 Osstell Beacon+, 103100 MEGA ISQ II, 104500 ISQTracker, 91060 NeoTell From class Im to class I