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	170781597
Effective date	2024-02-21
Expiry date	2027-01-05
Frankfurt am Main,	2024-02-21

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Annex to EU Quality Management Certificate
SRN of Manufacturer: SE-MF-000002162
Certificate ID: 170781597

Device categories and variants covered by this certificate:

Device category:	**MDA 0311 - Active non-implantable dental devices**
Product name:	103000 Osstell Beacon+, 103100 MEGA ISQ II, 104500 ISQTracker, 91060 NeoTell
Risk classification:	Im
Basic-UDI-DI:	9010522Beacon5V
Intended purpose:	Intended for use as a Dental Implant Stability Analyzer

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 Type A3, SmartPeg Type 1-18, 21-28, 30-38, 40, 45-55, 57-58, 60-69, 73-97, 99-104, 106-111, SmartPeg Type 6 - DIO, SmartPeg Type 22 - DIO, SmartPeg Type 18 - Neoss SP, SmartPeg 38 Neoss NP, SmartPeg Type 52 Neoss Access Abutment, SmartPeg Type 98 Neoss MUA
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 the case of devices with a measuring function, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects related to the conformity of the devices with the metrological requirements.

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