EU-Quality Management Certificate

This is to certify that the company

Osstell AB

Stampgatan 14
41101 Göteborg
Sweden

has implemented a complete Quality Management System for each phase from Design to Final Testing of the products.

Through an audit, documented in a report, carried out by DQS Medizinprodukte GmbH, the proof was provided that this quality management system meets the requirements according to

Annex IX of the Regulation (EU) 2017/745

CONFORMITY ASSESSMENT PROCEDURE ON THE BASIS OF A QUALITY MANAGEMENT SYSTEM AND AN ASSESSMENT OF THE TECHNICAL DOCUMENTATION

regarding the medical devices listed in the Annex:
The manufacturer shall be subject to surveillance in accordance with Annex IX, Chapter 1, Section 3.
The CE marking with the identification number of the Notified Body (0297) may be affixed on the devised listed on the certificate.

In case of devices placed on the market in sterile condition, devices with a measuring function or for devices which are reusable surgical instruments, the involvement of the Notified Body in these procedures shall be limited: in case of products that are placed on the market in sterile condition, limited to the aspects of manufacture concerned with securing and maintaining sterile condition; in the case of devices with a measuring function limited to the aspects related to the conformity of the devices with the metrological requirements; in the case of reusable surgical instruments limited to the aspects related to reuse, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, as well as the related instructions for use.

Certificate registration no.	SE-MF-000002162
Certificate ID	170779326
Previous certificate-ID	170776720
Effective date	2022-01-06
Expiry date	2027-01-05
Frankfurt am Main,	2022-01-06

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

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.

420.90 Version 1.0

Annex to EU Quality Management Certificate
Certificate registration No.: SE-MF-000002162
Certificate ID: 170779326
Effective date: 2022-01-06

Osstell AB

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Product name	Devices	Risk class	Intended Use
Dental implant stability measurement devices with accessories	Osstell Beacon	Im	Intended for use as a dental implant stability analyzer.
Measurement accessories for dental implant stability measurement devices	Osstell SmartPegs	Is	Intended for use as accessories for Osstell instruments for measuring implant stability

Examinations and tests performed (e.g. Reference to relevant CS, harmonised standards, test reports and audit report):
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

Reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device or devices covered:
n/a