EU Quality Management Certificate

This is to certify that the company

Max Stäubli AG

Spätzstrasse 14
8810 Horgen
Switzerland

SRN: CH-MF-000013911

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.

For placing of devices of class IIa, IIb or III listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	549410 MDR2017Q
Certificate ID	170782451
Effective date	2023-06-30
Expiry date	2028-06-29
Frankfurt am Main,	2023-06-30

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)

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 this certificate can only be verified by the QR-code.

420.90 Version 5.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: CH-MF-000013911
Certificate ID: 170782451

Authorised Representative of the company:

MED-RAS GmbH

Eichenallee 8
211521 Wohltorf
Germany

SRN: DE-AR-000006211

Device categories covered by this certificate:

Device category:	**MDN1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**
Risk classification:	Is
Intended purpose:	The catheter valve (CV) is used to close the bladder catheter. It is pushed onto the catheter tube and thus enables the patient to empty the bladder (micturition) in a self-determined, controlled manner. The application takes place outside the human body.

Examinations and tests performed:
549410_A211709MED_01 dated 2023-03-26

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.
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	n/a	n/a	n/a