EU Quality Management Certificate

This is to certify that the company

Bürki inno med AG

Industriestrasse 67
9443 Widnau
Switzerland

SRN: CH-MF-000017443

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.	527033 MDR2017Q
Certificate ID	1000126483
Effective date	2025-10-23
Expiry date	2030-10-22
Frankfurt am Main,	2025-10-23

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: CH-MF-000017443
Certificate ID: 1000126483

Authorised Representative of the company:

Bürko inno med GmbH

Im Schaffner 47/1
69123 Heidelberg, DE

SRN: DE-AR-000008073

Device categories and variants covered by this certificate:

Device category:	**MDN 1206 - Non-active non-implantable ophthalmologic devices**
Product name:	I/A System Reusable
Risk classification:	Ir
Basic-UDI-DI:	764013745P02P04X4
Intended purpose:	The reusable irrigation /aspiration systems are intended to be used to deliver solutions to the eye and to extract solutions and residuals of tissue from the eye during cataract operations in the anterior chamber. The instruments are connected to the aspiration / irrigation system by standard Luer-cones. The reusable irrigation / aspiration systems are intended to be used only by appropriately specialist surgeon.

Examinations and tests performed:
527033_A212923MED dated 2023-10-27
527033_A212923MED "I/A System Reusable, I(r)" dated 2025-09-19

Further conditions for or limitations to the validity of the certificate:
In the case of reusable surgical instruments, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects related to reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing, as well as the related instructions for use.

Reference to previous certificates:

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