

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service.

Manufacturer name	Bürki inno med AG
Manufacturer address and contact details	Industriestrasse 67 9443 Widnau Switzerland
Single Registration Number (SRN) (if available)	CH-MF-000017443

Authorised Representative name (if applicable)	Bürki inno med GmbH
Authorised Representative address and contact details	Im Schaffner 47/1 69123 Heidelberg
Single Registration Number (SRN) (if available)	DE-AR-000008073

Notified body name (if applicable)	DQS Medizinprodukte GmbH
Notified body number (if applicable)	0297
Directive Certificate number(s) to which this confirmation is made (if applicable)	527033 MR2 Certificate unique ID: 170710228
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2023-12-09
End date of extended validity/transition period	31.12.2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.
 - Expired/expires *after* 20 March 2023:
 - Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➤ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR is in place.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Bürki inno med AG

Location & Date: Widnau, Switzerland; 2024-01-11*

Signature, Print Name, Title: Gianni Müller, CEO



Contact Details (at least email): info@buerki.eu

**This version of the declaration replaces the initial declaration, issued on 2023-10-16*

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Ophthalmic Cannulae; Bimanual Irrigation /Aspiration Single Use Instruments; Sets STERILE	527033 MR2 Certificate unique ID: 170710228	2023-12-09	DQS Medizinprodukte GmbH, no. 0297	DQS Medizinprodukte GmbH, no. 0297	31.12.2028	n.a.
Ophthalmic Cannulae; Coaxial Irrigation / Aspiration Single Use Instruments STERILE	527033 MR2 Certificate unique ID: 170710228	2023-12-09	DQS Medizinprodukte GmbH, no. 0297	DQS Medizinprodukte GmbH, no. 0297	31.12.2028	n.a.
Bimanual & Coaxial Irrigation / Aspiration Reusable Instruments	527033 MR2 Certificate unique ID: 170710228	2023-12-09	DQS Medizinprodukte GmbH, no. 0297	DQS Medizinprodukte GmbH, no. 0297	31.12.2028	n.a.

Product variants of the above listed devices are listed in **Annex A** to this manufacturer's declaration.