

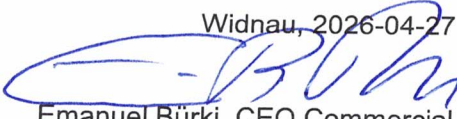
DECLARATION OF CONFORMITY

We declare on our sole responsibility that the medical devices listed in Annex A of this document are class Ir and comply with the General Safety and Performance Requirements (Annex I) of Regulation (EU) 2017/745 (MDR) for medical devices.

Manufacturer	Bürki inno med AG Industriestrasse 67 9443 Widnau Switzerland		
Single Registration Number (SRN) of manufacturer	CH-MF-000017443		
EC-REP Authorized representative	Bürki inno med GmbH Im Schaffner 47/1 69123 Heidelberg Germany		
SRN of authorized representative	DE-AR-000008073		
Product family	I/A System reusable		
Basic UDI-DI	764013745P02P04X4		
Product risk class	Ir (MDR Annex VIII, rule 6, sub-clause 2)		
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 surgeons.		
Product variants	See Annex A		
Name of Notified Body	DQS Medizinprodukte GmbH August-Schanz-Straße 21 60433 Frankfurt am Main Germany		CE ₀₂₉₇
Identification number of Notified Body	0297		
Regulation / standard	Date of certificate	Valid until	Certificate no.
(EU) 2017/745 (MDR) Annex IX	2025-10-23	2030-10-22	1000126483
EN ISO 13485:2016 + A11:2021	2024-12-10	2027-12-09	1000187929
Compliant standards	EN ISO 14971:2019/A11:2021 EN ISO 17664-1:2021 EN ISO 17665:2024		

The conformity of the products with the applicable provisions of Annex IX (excluding section 5) of Regulation (EU) 2017/745 (MDR) is declared by affixing the CE marking.

This declaration of conformity is valid until 2030-10-22.

Widnau, 2026-04-27

 Emanuel Bürki, CEO Commercial
 Bürki inno med AG

Annex A to the Declaration of Conformity I/A System reusable

Basic-UDI-DI: 764013745P02P04X4

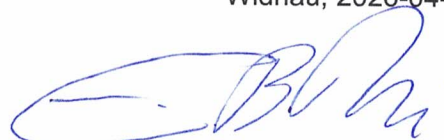
Product family	Art. number	Description of product variant	
I/A System reusable – monomanual (coaxial) variants	SL 100	I/A Handle, monomanual (coaxial, safe-lock)	
	SL 110	I/A Tip, straight, 16G (Ø1.60mm), metal sleeve, asp. port Ø0.35mm, dual-side irrigation ports Ø0.98mm	
	SL 110/0.3	I/A Tip, straight, 16G (Ø1.60mm), metal sleeve, asp. port Ø0.30mm, dual-side irrigation ports Ø0.98mm	
	SL 115	I/A Tip, straight, 16G (Ø1.60mm), metal sleeve, asp. port Ø0.50mm, dual-side irrigation ports Ø0.98mm	
	SL 116	I/A Tip, straight, for silicone sleeve irrigation, 19G (Ø1.00mm), asp. port Ø0.35mm	
	SL 116 s1	I/A Tip, straight, for silicone sleeve irrigation, 22G (Ø0.70mm), asp. port Ø0.30mm	
	SL 116 s2	I/A Tip, straight, for silicone sleeve irrigation, 21G (Ø0.80mm), asp. port Ø0.30mm	
	SL 116 s3	I/A Tip, straight, for silicone sleeve irrigation, 20G (Ø0.90mm), asp. port Ø0.30mm	
	SL 116 s4	I/A Tip, straight, for silicone sleeve irrigation, 19G (Ø1.00mm), asp. port Ø0.30mm	
	SL 117	I/A Tip, straight, for silicone sleeve irrigation, 20G (Ø0.90mm), asp. port Ø0.33mm	
	SL 118 c1	I/A Tip, curved, for silicone sleeve irrigation, 22G (Ø0.70mm), asp. port Ø0.30mm	
	SL 118 c2	I/A Tip, curved, for silicone sleeve irrigation, 21G (Ø0.80mm), asp. port Ø0.30mm	
	SL 118 c3	I/A Tip, curved, for silicone sleeve irrigation, 20G (Ø0.90mm), asp. port Ø0.30mm	
	SL 118 c4	I/A Tip, curved, for silicone sleeve irrigation, 19G (Ø1.00mm), asp. port Ø0.30mm	
	SL 119	I/A Tip, angled 45°, for silicone sleeve irrigation, 19G (Ø1.00mm), asp. port Ø0.35mm	
	SL 119 a11	I/A Tip, angled 30°, for silicone sleeve irrigation, 22G (Ø0.70mm), asp. port Ø0.30mm	
	SL 119 a12	I/A Tip, angled 30°, for silicone sleeve irrigation, 21G (Ø0.80mm), asp. port Ø0.30mm	
	SL 119 a13	I/A Tip, angled 30°, for silicone sleeve irrigation, 20G (Ø0.90mm), asp. port Ø0.30mm	
	SL 119 a14	I/A Tip, angled 30°, for silicone sleeve irrigation, 19G (Ø1.00mm), asp. port Ø0.30mm	
	SL 119 a21	I/A Tip, angled 45°, for silicone sleeve irrigation, 22G (Ø0.70mm), asp. port Ø0.30mm	
	SL 119 a22	I/A Tip, angled 45°, for silicone sleeve irrigation, 21G (Ø0.80mm), asp. port Ø0.30mm	
	SL 119 a23	I/A Tip, angled 45°, for silicone sleeve irrigation, 20G (Ø0.90mm), asp. port Ø0.30mm	
	SL 119 a24	I/A Tip, angled 45°, for silicone sleeve irrigation, 19G (Ø1.00mm), asp. port Ø0.30mm	
	SL 120 45°	I/A Tip, angled 45°, 16G (Ø1.60mm), metal sleeve, asp. port Ø0.35mm, dual-side irrigation ports Ø0.98mm	
	SL 120 30°	I/A Tip, angled 30°, 16G (Ø1.60mm), metal sleeve, asp. port Ø0.30mm, dual-side irrigation ports Ø0.98mm	
	SL 130	I/A Tip, angled 90°, 16G (Ø1.60mm), metal sleeve, asp. port Ø0.35mm, dual-side irrigation ports Ø0.98mm	
	SL 140	I/A Tip, curved, 16G (Ø1.60mm), metal sleeve, asp. port Ø0.35mm, dual-side irrigation ports Ø0.98mm	
	1901-5000	I/A Coaxial Sophi MU Handle (identical attributes as SL 100: I/A Handle, monomanual (coaxial, safe-lock))	
	1901-5020	I/A Coaxial Sophi MU Tip 45° 20G (identical attributes as SL 119 a23: I/A Tip, angled 45°, for silicone sleeve irrigation, 20G (Ø0.90mm), asp. port Ø0.30mm)	
	1901-5021	I/A Coaxial Sophi MU Tip 45° 21G (identical attributes as SL 119 a22: I/A Tip, angled 45°, for silicone sleeve irrigation, 21G (Ø0.80mm), asp. port Ø0.30mm)	
	1901-5022	I/A Coaxial Sophi MU Tip 45° 22G (identical attributes as SL 119 a21: I/A Tip, angled 45°, for silicone sleeve irrigation, 22G (Ø0.70mm), asp. port Ø0.30mm)	
	I/A System reusable – bimanual variants (T)	BA 100/T	Aspiration Handpiece 21G (Ø0.80mm), polished tip, asp. port Ø0.30mm
		BA 102/T	Aspiration Handpiece 21G (Ø0.80mm), polished tip, asp. port Ø0.40mm
		BA 104/T	Aspiration Handpiece 21G (Ø0.80mm), polished tip, asp. port Ø0.50mm
		BA 105/T	Aspiration Handpiece 21G (Ø0.80mm), rough tip, asp. port Ø0.30mm
		BA 107/T	Aspiration Handpiece 21G (Ø0.80mm), rough tip, asp. port Ø0.40mm
		BA 108/T	Aspiration Handpiece 20G (Ø0.90mm), rough tip, asp. port Ø0.35mm
		BA 113/T	Aspiration Handpiece 23G (Ø0.65mm), polished tip, asp. port Ø0.30mm
		BA 114/T	Aspiration Handpiece 23G (Ø0.65mm), rough tip, asp. port Ø0.30mm
		BA 118/T	Aspiration Handpiece 22G (Ø0.70mm), polished tip, asp. port Ø0.35mm
		BA 119/T	Aspiration Handpiece 22G (Ø0.70mm), rough tip, asp. port Ø0.35 mm
BAO 100/T		Aspiration Handpiece oval cannula (0.95x0.55mm), matt finish, asp. port Ø0.30mm	
BAO 102/T		Aspiration Handpiece oval cannula (1.10x0.70mm), matt finish, rough tip, asp. port Ø0.35mm	
BAO 105/T		Aspiration Handpiece oval cannula (0.95x0.55mm), matt finish, rough tip, asp. port Ø0.30mm	
BAO 110/T		Aspiration Handpiece oval cannula (based on 21G), matt finish, rough tip, asp. port Ø0.30mm	
BI 120/T		Irrigation Handpiece 21G (Ø0.80mm), polished tip, dual-side ports Ø0.50mm	
BI 121/T		Irrigation Handpiece 20G (Ø0.90mm), polished tip, dual-side ports Ø0.65mm (high-flow)	
BI 123/T		Irrigation Handpiece 23G (Ø0.65mm), polished tip, dual-side ports Ø0.35mm	
BI 124/T		Irrigation Handpiece 23G (Ø0.65mm), polished tip, tip with open end 45°	
BI 125/T		Irrigation Handpiece 21G (Ø0.80mm), rough tip, dual-side ports Ø0.50mm	
BI 126/T		Irrigation Handpiece 20G (Ø0.90mm), polished tip, tip with open end 45° (high-flow)	
BI 128/T	Irrigation Handpiece 22G (Ø0.70mm), polished tip, dual-side ports Ø0.45mm		

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Product family	Art. number	Description of product variant	
	BI 129/T	Irrigation Handpiece 22G (Ø0.70mm), polished tip, tip with open end 45°	
	BI 140/T	Irrigation Handpiece 21G (Ø0.80mm), polished tip, tip with open end 45°	
	BIO 120/T	Irrigation Handpiece oval cannula (0.95x0.55mm), matt finish, irrig. port Ø0.55mm	
	BIO 122/T	Irrigation Handpiece oval cannula (0.95x0.55mm), matt finish, dual-side ports 0.55x0.35mm	
	BIO 127/T	Irrigation Handpiece oval cannula (1.10x0.70mm), matt finish, tip with open end 30° (high flow)	
	BIO 128/T	Irrigation Handpiece oval cannula (based on 21G), matt finish, proximal TWIN-PORTs Ø0.55mm	
	1901-5321	I/A Bimanual Sophi MU IRR Polished 21G (identical attributes as BI 120/T: Irrigation Handpiece 21G (Ø0.80mm), polished tip, dual-side ports Ø0.50mm)	
	1901-5421	I/A Bimanual Sophi MU IRR Rough 21G (identical attributes as BI 125/T: Irrigation Handpiece 21G (Ø0.80mm), rough tip, dual-side ports Ø0.50mm)	
	1901-5623	I/A Bimanual Sophi MU IRR Polished 23G (identical attributes as BI 124/T: Irrigation Handpiece 23G (Ø0.65mm), polished tip, tip with open end 45°)	
	1901-5523	I/A Bimanual Sophi MU ASP Rough 23G (identical attributes as BA 114/T: Aspiration Handpiece 23G (Ø0.65mm), rough tip, asp. port Ø0.30mm)	
	1901-5821	I/A Bimanual Sophi MU ASP Polished 21G (identical attributes as BA 100/T: Aspiration Handpiece 21G (Ø0.80mm), polished tip, asp. port Ø0.30mm)	
	1901-5921	I/A Bimanual Sophi MU ASP Rough 21G (identical attributes as BA 105/T: Aspiration Handpiece 21G (Ø0.80mm), rough tip, asp. port Ø0.30mm)	
	I/A System reusable – bimanual variants (A)	BA 200/A	Aspiration Handpiece 21G (Ø0.80mm), polished tip, asp. port Ø0.35mm
		BA 213/A	Aspiration Handpiece 23G (Ø0.65mm), polished tip, asp. port Ø0.30mm
BA 218/A		Aspiration Handpiece 22G (Ø0.70mm), polished tip, asp. port Ø0.35mm	
BA 205/A		Aspiration Handpiece 21G (Ø0.80mm), rough tip, asp. port Ø0.35mm	
BA 214/A		Aspiration Handpiece 23G (Ø0.65mm), rough tip, asp. port Ø0.30mm	
BA 219/A		Aspiration Handpiece 22G (Ø0.70mm), rough tip, asp. port Ø0.35mm	
BA 260/A		Aspiration Handpiece angled right (R) 25G (Ø0.50mm), asp. port 0.60x0.25mm	
BA 261/A		Aspiration Handpiece angled left (L) 25G (Ø0.50mm), asp. port 0.60x0.25mm	
BI 220/A		Irrigation Handpiece 21G (Ø0.80mm), polished tip, dual-side ports Ø0.45mm	
BI 223/A		Irrigation Handpiece 23G (Ø0.65mm), polished tip, dual-side ports Ø0.35mm	
BI 224/A		Irrigation Handpiece 23G (Ø0.65mm), polished tip, tip with open end 45°	
BI 228/A		Irrigation Handpiece 22G (Ø0.70mm), polished tip, dual-side ports Ø0.45mm	
BI 229/A		Irrigation Handpiece 22G (Ø0.70mm), polished tip, tip with open end 45°	
BI 240/A		Irrigation Handpiece 21G (Ø0.80mm), polished tip, tip with open end 45°	

Widnau, 2026-04-27



Emanuel Bürki, CEO Commercial
Bürki inno med AG