

## DECLARATION OF CONFORMITY

**Bürki inno med AG**  
**Industriestrasse 67**  
**9443 Widnau / Switzerland**

We declare on our sole responsibility that the medical devices listed in Annex A of this document are class IIa and comply with the essential requirements (Annex I) of Directive 93/42/EEC as amended by Annex II of Directive 2007/47/EC.

Notified Body	DQS Medizinprodukte GmbH August-Schanz-Strasse 21 60433 Frankfurt am Main Germany		
<b>Directive/ Standard</b>	<b>Date of Certification</b>	<b>Valid until</b>	<b>Certificate no.</b>
Annex II, Directive 93/42/EEC	2019-11-18	2023-12-09	527033 MR2
EN ISO 13485 : 2016 + AC : 2016	2021-12-10	2024-12-09	527033 MP2016

The conformity of the products with the applicable provisions of Annex II (excluding section 4) of Directive 93/42/EEC is declared by affixing the CE marking

This declaration of conformity is valid until 2023-12-09.



Bürki inno med AG

Widnau, November 29<sup>th</sup>, 2021

Gianni Müller, CEO Commercial

## Annex A

Product family	Type
<b>Irrigation / Aspiration Products - Monomanual / Coaxial - Reusable</b>	<ul style="list-style-type: none"> <li>- SL 100 I/A Handpiece disassembling; coaxial / monomanual</li> <li>- SL 110 Straight Tip for standard aspiration, ; 16G, Asp. 0.35mm, D 1.6mm</li> <li>- SL 110/0.3 Straight Tip 16G for standard aspiration; 16G, Asp. 0.30mm, D 1.6mm</li> <li>- SL 115 Straight Tip 16G for removal of viscoelastic fluid; Asp.port 0.50mm</li> <li>- SL 116 Straight Si-Sleeve Tip; 21G, Asp. 0.35</li> <li>- SL 116 s1 Straight Si-Sleeve Tip 22G AspPort 0.30mm D 0.70mm</li> <li>- SL 116 s2 Straight Si-Sleeve Tip 21G AspPort 0.30mm D 0.80mm</li> <li>- SL 116 s3 Straight Si-Sleeve Tip 20G AspPort 0.30mm D 0.90mm</li> <li>- SL 116 s4 Straight Si-Sleeve / 0.3 D1.0 straight</li> <li>- SL 117 Straight Si-Sleeve Tip 20G</li> <li>- SL 118 c1 Curved Si-Sleeve Tip 22G AspPort 0.30mm D 0.70mm</li> <li>- SL 118 c2 Curved Si-Sleeve Tip 21G AspPort 0.30mm D 0.80mm</li> <li>- SL 118 c3 Curved Si-Sleeve Tip 20G AspPort 0.30mm D 0.90mm</li> <li>- SL 118 c4 Curved Si-Sleeve Tip, AspPort 0.30mm D 1.0mm</li> <li>- SL 119 Angled Si-Sleeve Tip 45°</li> <li>- SL 119 a11 Angl 30°Si-Sleeve Tip 22G, AspPort 0.30mm D 0.7mm</li> <li>- SL 119 a12 Angl 30°Si-Sleeve Tip 21G AspPort 0.30mm D 0.80mm</li> <li>- SL 119 a13 Angl 30°Si-Sleeve Tip 20G AspPort 0.30mm D 0.90mm</li> <li>- SL 119 a14 Angl 30°Si-Sleeve Tip AspPort 0.30mm D 1.0mm</li> <li>- SL 119 a21 Angl 45°Si-Sleeve Tip 22G, AspPort 0.30mm D 0.7mm</li> <li>- SL 119 a22 Angl 45°Si-Sleeve Tip 21G AspPort 0.30mm D 0.80mm</li> <li>- SL 119 a23 Angl 45°Si-Sleeve Tip 20G AspPort 0.30mm D 0.90mm</li> <li>- SL 119 a24 Angl 45°Si-Sleeve Tip AspPort 0.30mm D 1.0mm</li> <li>- SL 120 30° Tip 30° 16G angled, Asp. port 0.35 mm; for peripheral cortex removal</li> <li>- SL 120 45° Tip 45° 16G for peripheral cortex removal</li> <li>- SL 130 Tip 90° 16G for peripheral &amp; superior cortex remove</li> <li>- SL 140 Curved Tip 16G (inn21G) for initial cortex removal</li> </ul>
<b>Irrigation / Aspiration Products - Bimanual - Reusable</b>	<ul style="list-style-type: none"> <li>- BA 100/T Aspiration Handle polished tip 21G</li> <li>- BA 102/T Aspiration Handle polished tip, 21G</li> <li>- BA 104/T Aspiration Handle polished tip 21G</li> <li>- BA 105/T Aspiration Handle rough tip 21G</li> <li>- BA 107/T Aspiration Handle rough tip 21G</li> <li>- BA 108/T Aspiration Handle rough tip 20G</li> <li>- BA 113/T Aspiration Handle polished tip, 23G; Asp. Port 0,30mm</li> <li>- BA 114/T Aspiration Handle rough tip 23G; Asp. Port 0.30mm</li> <li>- BA 118/T Aspiration Handle polished tip 22G; Asp. Port 0.35mm</li> <li>- BA 119/T Aspiration Handle rough tip 22G; Asp. Port 0.35mm</li> <li>- BAO 100/T Aspiration Handle oval cannula</li> <li>- BAO 102/T Aspiration Handle oval cannula</li> <li>- BAO 105/T Aspiration Handle oval cannula</li> <li>- BAO 110/T Aspiration Handle, elliptical cannula 21G, rough</li> <li>- BA 200/A Aspiration Handle polished tip 21G</li> <li>- BA 205/A Aspiration Handle rough tip 21G</li> <li>- BA 213/A Aspiration Handle polished tip 23G</li> <li>- BA 214/A Aspiration Handle rough tip 23G</li> <li>- BA 218/A Aspiration Handle polished tip 22G</li> <li>- BA 219/A Aspiration Handle rough tip 22G</li> <li>- BI 120/T Irrigation Handle polished tip 21G</li> <li>- BI 121/T Irrigation Handle polished tip 20G</li> <li>- BI 123/T Irrigation Handle polished tip, 23G, dual side ports 0.35mm</li> <li>- BI 124/T Irrigation Handle polished tip, 23G, open end 45°</li> <li>- BI 125/T Irrigation Handle rough tip 21G</li> <li>- BI 126/T Irrigation Handle open end tip 45° 20G</li> <li>- BI 128/T Irrigation Handle polished tip, 22G, dual side ports 0.45mm</li> <li>- BI 129/T Irrigation Handle polished tip, 22G, open end 45°</li> <li>- BI 140/T Irrigation Handle polished tip 21G</li> <li>- BIO 120/T Irrigation Handle oval cannula, mate finish tip</li> <li>- BIO 122/T Irrigation Handle oval cannula</li> <li>- BIO 127/T Irrigation Handle oval cannula, mate finish</li> <li>- BIO 128/T Irrigation Handle elliptical cannula 21G; Twin Ports 0.55mm</li> <li>- BI 220/A Irrigation Handle polished tip 21G</li> <li>- BI 223/A Irrigation Handle polished tip 23G dual side ports</li> </ul>

Product family	Type
	<ul style="list-style-type: none"> <li>- BI 224/A Irrigation Handle polished tip 23G open end tip</li> <li>- BI 228/A Irrigation Handle polished tip 22G dual side ports</li> <li>- BI 229/A Irrigation Handle polished tip 22G open end tip</li> <li>- BI 240/A Irrigation Handle polished tip 21G</li> </ul>
<b>Irrigation / Aspiration - Monomanual / Coaxial - single use</b>	<ul style="list-style-type: none"> <li>- CX2045-P Coaxial System Disposable 20G; Asp. port 0.35mm, angled 45°, POLISHED</li> <li>- CX2045-R Coaxial System Disposable 20G; Asp. port 0.35mm, angled 45°, ROUGH</li> <li>- CX2065-P Coaxial System Disposable 20G; Asp. port 0.35mm, angled 65°, POLISHED</li> <li>- CX2065-R Coaxial System Disposable 20G; Asp. port 0.35mm, angled 65°, ROUGH</li> <li>- CX2145-P Coaxial System Disposable 21G; Asp. port 0.35mm, angled 45°, POLISHED</li> <li>- CX2145-R Coaxial System Disposable 21G; Asp. port 0.35mm, angled 45°, ROUGH</li> <li>- CX2165-P Coaxial System Disposable 21G; Asp. port 0.35mm, angled 65°, POLISHED</li> <li>- CX2165-R Coaxial System Disposable 21G; Asp. port 0.35mm, angled 65°, ROUGH</li> <li>- CX2245-P Coaxial System Disposable 22G; Asp. port 0.35mm, angled 45°, POLISHED</li> <li>- CX2245-R Coaxial System Disposable 22G; Asp. port 0.35mm, angled 45°, ROUGH</li> <li>- CX2265-P Coaxial System Disposable 22G; Asp. port 0.35mm, angled 65°, POLISHED</li> </ul>
<b>Irrigation / Aspiration - Bimanual System - single use</b>	<ul style="list-style-type: none"> <li>- BSD 500 Bimanual System Disposable 21G</li> <li>- BSD 510 Bimanual System Disposable 21G</li> <li>- BSD 515 Bimanual System Disposable 21G</li> <li>- BSD 522 Bimanual System Disposable 23G</li> <li>- BSD 540 Bimanual System Disposable 22G</li> <li>- BSD 541 Bimanual System Disposable 22G</li> <li>- BSD 542 Bimanual System Disposable 22G</li> <li>- BSD 560 Bimanual System Disposable 20G</li> <li>- BSD 565 Bimanual System Disposable 20G</li> <li>- BSD 600 Bimanual System Disposable 21G elliptic</li> </ul>