DQS GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

Bürki inno med AG
Industriestrasse 67
9443 Widnau (SG)
Schweiz

Our ref.: MRE, phone: +49 69 95427-8220
E-Mail: wahidali.majid@dqs.de

Frankfurt a. M.,
2025-03-06

Ref. 527033
Assessment according to ISO 13485, Annex II Directive 93/42/EEC Medical devices, Regulation (EU) 2017/745 Annex IX - Assessment of technical documentation, Regulation (EU) 2017/745 Annex IX - Quality management system

To whom it may concern

We hereby confirm that the assessment according to ISO 13485, Annex II RL 93/42/EEC Medical Devices, Regulation (EU) 2017/745 Annex IX - Assessment of Technical Documentation, Regulation (EU) 2017/745 Annex IX - Quality Management System at the company:

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was conducted in 2023 and 2024. The company has long since applied to the DQS for MDR approval. The company will receive the MDR certificate as soon as possible.

Yours sincerely,

DQS Medizinprodukte GmbH

AJIT KHADKA
Regulatory Affairs Manager