Certificate

mdc medical device certification GmbH

medesign Ingenieur Consulting GmbH Dietramszeller Straße 6 83623 Dietramszell-Linden Germany

for the scope

development, production and distribution of medical devices for gynaecology and urology (pessaries, vaginal and anal dilators, medical lubricating gels) and accessories

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from

2019-02-11

Valid until Registration no.

2021-01-21 D1016100016

Report no.

P18-01096-126973

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MLC



Head of Certification Body



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