## Certificate

mdc medical device certification GmbH certifies that

## Colenta Labortechnik GmbH & Co. KG Neunkirchner Straße 117 2700 Wiener Neustadt Austria

for the scope

manufacture and distribution of medical X-ray films; design, development, manufacture, installation, distribution and service of X-ray system control software and software for transmission and archiving of X-ray image data

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 Valid until Registration no. Report no. Stuttgart 2020-03-15 2023-03-14 D4004500006 P19-01560-160092 2020-01-22

Head of Certification Body





mdc medical device certification GmbH Kriegerstraße 6 D-70191 Stuttgart, Germany Phone: +49-(0)711-253597-0 Fax: +49-(0)711-253597-10 Internet: http://www.mdc-ce.de

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