

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	2020-03-15
Valid until	2023-03-14
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Stuttgart	2020-01-22



Head of Certification Body

