

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

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



Head of Certification Body



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