

# 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
Registration no.	D4004500006
Report no.	P19-01560-160092
Stuttgart	2020-01-22



Head of Certification Body

