

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 transport 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 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Valid from	2017-03-14
Valid until	2020-03-14
Registration no.	D4004500001
Report no.	P16-01600-84569
Stuttgart	2017-03-14



Head of Certification Body

