

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
123925-2012-AQ-GER-DAkKS

Initial certification date:
03. January 2001

Valid:
01. March 2019 - 28. February 2022

This is to certify that the management system of

Colenta Labortechnik GmbH & Co. KG

Neunkirchner Str. 117, 2700 Wiener Neustadt, Austria

has been found to conform to the Quality Management System standard:

ISO 9001:2015

This certificate is valid for the following scope:

Design and production of automatic exposure systems and processing equipments for all kind of light-sensitized materials as well as distribution and trading of accessories and consumables

Place and date:
Essen, 07. February 2019



Deutsche
Akkreditierungsstelle
D-ZM-18453-01-00

For the issuing office:
DNV GL - Business Assurance
Schnieringshof 14, 45329 Essen, Germany

Thomas Beck
Technical Manager

Digitally signed by Matei Vasile
Date: 2019.11.26 23:34:40 EET



Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV GL Business Assurance Zertifizierung und Umweltgutachten GmbH, Schnieringshof 14, 45329 Essen, Germany.
TEL: +49 201 7296-222. www.dnvgl.de/assurance

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

