

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

Colenta Labortechnik GmbH & Co. KG
Neunkirchner Straße 117
2700 Wiener Neustadt
Austria

for the scope

Picture Archiving and Communication Systems, Radiology
X-ray and digitalisation system
(see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2017-05-30
Valid until	2022-05-30
Registration no.	D4004500002
Report no.	P16-01600-98426
Stuttgart	2017-05-30


Head of Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

Attachment of the certificate

No. D4004500002

Date 2017-05-30

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Product category	Product	Class	Product-code
Picture Archiving and Communication Systems, Radiology	DX Easy Imaging X-AQS, X-PACS, X-AQS PACS and digitalisation subsystems: DX Easy Imaging CR 3X-Pro DX Easy Imaging CR Smart DX Easy Imaging CR Retrofit Kit DX Easy Imaging CR Premium DX Easy Imaging CR Retrofit Kit HighCap XLr DX Easy Imaging CR Retrofit Kit HighCap Xr DX Easy Imaging DR Retrofit Kit VW 1417-W DX Easy Imaging DR Retrofit Kit VW 1417-WL DX Easy Imaging DR Retrofit Kit RA 1717-W DX Easy Imaging DR Retrofit Kit KM 1417-WL DX Easy Imaging DR Retrofit Kit KM 1717-WL DX Easy Imaging DR Retrofit Kit PE 1417-WL DX Easy Imaging DR Retrofit Kit PE 1717-W	IIb	16-247
X-ray and digitalisation system	System DX Easy Imaging Standard CR/DR System DX Easy Imaging Classic CR/DR	IIb	17-904





 Head of Certification Body