

# 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



  
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 Head of Certification Body