

# 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

**Software for**  
**Picture Archiving and Communication Systems, Radiology**  
**(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	2021-05-18
Valid until	2024-05-26
Registration no.	D4004500008
Report no.	P21-00631-202930
Stuttgart	2021-05-18

Head of Certification Body



**Attachment of the certificate**

**No. D4004500008**

Date 2021-05-18

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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 Retrofit Kit HighCap XLr DX Easy Imaging CR Retrofit Kit HighCap Xr DX Easy Imaging DR Retrofit Kit 1417-WL DX Easy Imaging DR Retrofit Kit 1717-WL	IIb	16-247



  
Head of Certification Body