

# 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

**X-ray Film, Sheet and  
intraoral dental radiographic film  
(see attachment)**

has introduced and applies a

## Quality System

for the manufacture of the products concerned and carries out a  
final inspection as specified in Annex V, Section 3.

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

**Annex V – Section 3**  
**of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

Valid from	2020-01-22
Valid until	2024-05-26
Registration no.	D4004500007
Report no.	P19-01560-160097
Stuttgart	2020-01-22



Head of Certification Body



**Attachment of the certificate**

**No. D4004500007**

Date 2020-01-22

Page 1 of 1

Product category	Product	Class	Product code
X-ray Film, Sheet	MEDIPHOT X-90/RP (BL1000) MEDIPHOT X-90N/RP (BL2000) MEDIPHOT X-O/RP (GR1000) MEDIPHOT X-OS/RP (GR2000) MEDIPHOT X-MA/RP (MA1000) MEDICAL X-RAY FILM (BL1000) MEDICAL X-RAY FILM (BL2000) MEDICAL X-RAY FILM (GR1000) MEDICAL X-RAY FILM (GR2000) MEDICAL X-RAY FILM (MA1000)	Ila	14-481
X-ray Film, intraoral dental radiographic film	MEDIPHOT DENT X-E	Ila	14-482



A handwritten signature in blue ink, consisting of stylized initials and a surname, is written above a horizontal line.

Head of Certification Body