

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 a series of loops and strokes, positioned above a horizontal line.

Head of Certification Body