

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	2017-05-30
Valid until	2022-05-30
Registration no.	D4004500003
Report no.	P16-01600-98971
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. D4004500003

Date 2017-05-30

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





Head of Certification Body