

# 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

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| Product category                               | Product  | Class | Product code |
|--|--|-------|--------------|
| X-ray Film, Sheet                              | MEDIPHOT X-90/RP (BL1000)<br>MEDIPHOT X-90N/RP (BL2000)<br>MEDIPHOT X-O/RP (GR1000)<br>MEDIPHOT X-OS/RP (GR2000)<br>MEDIPHOT X-MA/RP (MA1000)<br>MEDICAL X-RAY FILM (BL1000)<br>MEDICAL X-RAY FILM (BL2000)<br>MEDICAL X-RAY FILM (GR1000)<br>MEDICAL X-RAY FILM (GR2000)<br>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