



COLENTA Labortechnik
GmbH & Co. KG

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EU DECLARATION OF CONFORMITY



We,

COLENTA Labortechnik GmbH & Co. KG
Neunkirchnerstr. 117
A-2700 Wiener Neustadt

herewith declare on our sole responsibility, that the products

MEDIPHOT Dry Laser Imaging Film

conform to the provisions of the following Regulation(s) and Directive(s).

Regulation:

Medical Device Regulation: REGULATION (EU) 2017/745
and their Annexes

Common specifications ("CS"):

No reference to any CS

Conformity Assessment Procedure for Regulation (EU) 2017/745: Annex IV

single registration number (SRN):	AT-MF-000016797
Basic UDI-DI:	912010420DLFilm43
Trade Name:	MEDIPHOT Dry Laser Imaging Film
Model Reference:	DLFilm
Classification (MDR, Annex VIII):	Class I (Rule 1)

Product details:

MEDIPHOT DL – Dry Laser Imaging Film	
Art.No.	Type
DL35x43 (REF no. 20104 20101)	MEDIPHOT DL – Dry Laser Imaging Film 35x43cm (14"x17") – 100 sheets
DL26x36 (REF no. 20104 20102)	MEDIPHOT DL – Dry Laser Imaging Film 26x36cm (10"x14") – 150 sheets
DL25x30 (REF no. 20104 20104)	MEDIPHOT DL – Dry Laser Imaging Film 25x30cm (10"x12") – 150 sheets
DL20x25 (REF no. 20104 20103)	MEDIPHOT DL – Dry Laser Imaging Film 20x25cm (8"x10") – 150 sheets

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Wiener Neustadt, 15.03.2023
(VALID UNTIL 14.03.2026)

2023-03-15 - Declaration of Conformity DL

Name: Kurt Nowak
Function: CEO