

EU DECLARATION OF CONFORMITY



We,

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

herewith declare on our sole responsibility, that the product

MEDIPHOT Dry Laser Imaging Film

conforms 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: TBD
Trade Name: MEDIPHOT Dry Laser Imaging Film
Model Number: DL, DLM
Classification (MDR, Annex VIII): Class I (Rule 1)



Nguyen Vu Kim Anh
GIÁM ĐỐC
Nguyễn Vũ Kim Anh

Wiener Neustadt, 21.05.2021
(VALID UNTIL 14.03.2023)

Name: Alexander Nowak
Function: Managing Director