

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

DICOM Printer HighCap Xp

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

Regulation:

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

Directive:

RoHS Directive: 2011/65/EU, (EU) 2015/863

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:	DICOM Printer HighCap Xp
Model Number:	HighCap Xp
Classification (MDR, Annex VIII):	Class I (Rule 13)

Wiener Neustadt, 21.05.2021
(VALID UNTIL 14.03.2023)

2021-05-21 - Declaration of Conformity Highcap Xp

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