Medoro

EC Declaration of Conformity

Manufacturer:	MEDORO s.r.o., Štrossova 567, Pardubice 530 03, IČO: 26002612
Product:	Medical instrument - Dicompass software with variants according to the annex
Purpose:	Specialized modular Dicompass software is designed to work with imagery data for diagnostic and therapeutic purposes in the healthcare domain.
Classification:	IIb

The product listed above meets the regulatory requirements directive with 93/42/EHS guidline - 2007/47/EHS revision and is safe to use in accordance with its intended use and under usual circumstances. The manufacturer has taken the necessary precautions to ensure the product's congruance with its technical documentation and essential requirements defined by directive 93/42/EHS guidline - 2007/47/EHS revision of the 268/2014 coll. law on medical devices, Government regulation 54/2015 coll. on technical requirements for medical devices, standards: EN ISO 13485, EN 62304, ČSN EN ISO 15223-1:2013, ČSN EN 62366-1:2016, ISO 14971:2012 as amended and MEDDEV-y: 2.7/1 rev.4, 2.12/1 rev.8, 2.12/2 rev.2.

This statement is issued by manufacturer on the basis of proving compliance with requirements of the Directive 93/42/EHS – revision 2007/47/EHS .

Certificate No.:	2018-MDD/QS-019
Issue date:	27.8.2018
Validity date:	26.8.2023
Notified body No:2265:	3EC International a.s., Hraničná 18, 821 05 Bratislava, SR, www.3ec.sk

Ondřej Koloničný
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CEO

Michal Seiner
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Manager of quality

Place, date: Pardubice, 1.9.2018

Annex to the Declaration of Conformity

List of variants medical software Dicompass.

Dicompass Gateway Archive

Dicompass Gateway WebViewer

Dicompass Camera

Dicompass Recorder