

EU Declaration of Conformity

Manufacturer:	MEDORO s.r.o., Štrossova 567, Pardubice 530 03, Česká republika IN: 26002612, TIN: CZ 26002612, SRN: CZ-MF-000024306
Product:	medical device - software Dicompass with variants according to the annex Basic UDI-DI:859421232DICOMPASSGM
Intended purpose:	The specialized modular software Dicompass is intended as a tool for working with image data for the purposes of diagnostic and therapeutic procedures in healthcare. Dicompass contains not only a DICOM viewer, but also modules for a complete solution for digitizing video from endoscopes, ultrasounds, microscopes, but also other devices that do not have a direct DICOM output, converting recordings from digital cameras, scanners and cameras to DICOM format (DICOMization). Dicompass also offers functions for radiodiagnostics and radiotherapy.
Classification:	Risk Class IIb, according to Annex VIII, Rule 11 of the 745/2017 MDR

This Declaration of Conformity is issued under the sole responsibility of the manufacturer MEDORO s.r.o. and declares that the aforementioned product complies with the Law No.375/2022 Coll. and 745/2017 MDR, including compliance with the general requirements for safety and efficiency, when used in accordance with the intended purpose.

The following standards were applied in the conformity assessment: ČSN EN ISO 10781:2016, ČSN EN ISO 12052:2018, ČSN EN ISO 13485:2016/A11:2022, ČSN EN ISO 14971:2020/A11:2022, ČSN EN ISO 15223-1:2022, ČSN EN ISO 20417:2021, ČSN EN ISO 62304:2007/A1:2016, ČSN EN ISO 62366-1:2019/A1:2021, ČSN EN ISO 82304-1:2018 and MEDDEV: 2.7/1 rev.4, 2.12/1 rev.8, 2.12/2 rev.2.

MEDORO s.r.o. proceeds with CE marking of the product according to the requirements of 745/2017 MDR.

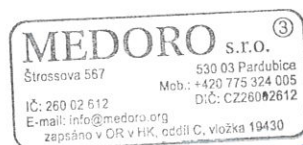
Method of conformity assessment: Annex IX - conformity assessment based on the quality management system and technical documentation assessment.

Certificate No.:	2022-MDR/QS-020
Issue date:	9.9.2022
Validity date:	9.9.2027
Notified body No:2265:	3EC International a.s., Hraničná 18, 821 05 Bratislava, SR, www.3ec.sk

Ondřej Koloničný



CEO



Michal Šeiner



Quality manager

Place, date: Pardubice, 22.12.2022



Annex to the Declaration of Conformity

List of variants medical software Dicompas:

- Dicompas Gateway
- Dicompas Camera 2