3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2022-MDR/QS-020

MEDORO s.r.o.
Štrossova 567, Pardubice 530 03, Czech Republic
SRN No.: CZ-MF-000024306

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of medical device:

software Dicompass, for variants, see Annex I

Intended purpose: See Annex II
MD class: IIb

meets the requirements on quality management system according to the Chapter I Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: **N/A**

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the MD Technical Documentation Assessment Report No. MDR118_2022_F18A_F18A_NR_SK_Sprava TF 2022 Medoro Final Review from 30.8.2022, MD Clinical Evaluation Report No. MDR118_2022_F21A NR_Správa z posúdenia klinického hodnotenia ZP MEDORO Dicompass Final from 30.8.2022 and MD Audit Report No. MDR118_2022 from 27.8.2022. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Notified body · 3EC International · NB 2265 · NOTIFIKOVANÁ OSOBA

Valid from: **9.9.2022**
Valid until: **9.9.2027**
First issue: **9.9.2022**
Revision: **00**
History: **See Annex III**

In Bratislava, Slovakia, 9.9.2022

3EC International a.s.
Dr. Katarína Tomin Srdošová
Director of NB2265

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-020

issued for the company

MEDORO s.r.o.

Štrossova 567, Pardubice 530 03, Czech Republic

List of medical devices covered by the EU Quality Management System Certificate: 2022-MDR/QS-020

Type No.	Trade Name	Other Trade Names
Dicompass	Dicompass Gateway	N/A
Dicompass	Dicompass Camera 2	N/A

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Dr. Katarína Tomin Srdošová
Director of NB2265

In Bratislava, Slovakia, 9.9.2022
Valid until 9.9.2027

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-020

issued for the company

MEDORO s.r.o.

Štrossova 567, Pardubice 530 03, Czech Republic

Intended purpose of medical devices covered by the EU Quality Management System Certificate: 2022-MDR/QS-020

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.

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

Dr. Katarína Tomin Srdošová
Director of NB2265

In Bratislava, Slovakia, 9.9.2022
Valid until 9.9.2027

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-020

issued for the company

MEDORO s.r.o.

Štrossova 567, Pardubice 530 03, Czech Republic

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2022-MDR/QS-020	9.9.2022	MDR118_2022	First issue

Notified body
3EC International
NB 2265
NOTIFIKOVANÁ OSOBA

Dr. Katarína Tomin Srdošová
Director of NB2265

In Bratislava, Slovakia, 9.9.2022
Valid until 9.9.2027