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

QUALITY MANAGEMENT SYSTEM CERTIFICATE OF IMPORTER AND DISTRIBUTOR

No. 2024-Art16/QS-001

This EU Quality Management System Certificate of Importer and Distributor confirms, that quality management system of Importer and Distributor of medical devices:

TIMED, s.r.o.

Seat: Trnavská cesta 112, 821 01 Bratislava, Slovak Republic
Dispensary of MD: Plynárenská 1, 821 01 Bratislava, Slovak Republic

SRN No.: SK-IM-000045572

meets the requirements on quality management system according to the Art. 16 sec. 3 of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended regarding:

MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters
MDA 0305 Active non-implantable devices for stimulation or inhibition
MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care
MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
MDN 1214 General non-active non-implantable devices used in health care and other nonactive non-implantable devices

for the following activities:

- provision, including translation, of the information supplied by the manufacturer, in accordance with Section 23 of Annex I of the Regulation (EU) 2017/745;
- changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State.

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 Importer and Distributor and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the Importer and Distributor is stated in the Audit Report No. SK-0837/24 from 12.12.2024.

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

Valid from: **19.12.2024**
Valid until: **19.12.2029**
First issue: **19.12.2024**
Revision: **00**

In Bratislava, Slovakia, 19.12.2024

3EC International a. s.
Katarína Tomin Srdošová, PhD.
Director of NB 2265

3EC®
international

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

QUALITY MANAGEMENT SYSTEM CERTIFICATE OF IMPORTER AND DISTRIBUTOR

No. 2024-Art16/QS-001

issued for the company

TIMED, s.r.o.

Seat: Trnavská cesta 112, 821 01 Bratislava, Slovak Republic
Dispensary of MD: Plynárenská 1, 821 01 Bratislava, Slovak Republic

Certificate History:

Revision	Quality Management System Certificate of importer / distributor reference	Date of issue	Number of Application on QMS certification of importer / distributor	Description
00	2024-Art16/QS-001	19.12.2024	Art16_004_2024	Initially granted certification

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

Valid from: **19.12.2024**
Valid until: **19.12.2029**
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In Bratislava, Slovakia, 19.12.2024

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