

CERTIFICATE



of the certification body for personnel of TÜV Thüringen e.V.

Mr. GHENADIE BERNIC

born: 1995-10-01 in: Ungheni, Republica Moldova

has successfully completed the course

Auditor for Medical Devices cf. ISO 13485

carried out by TÜV Thüringen Karpat S.R.L.

in Bukarest from 2023-10-04 – 2023-10-06

Education contents:

- General view of ISO 13485:2016 and of the Annex A11:2021 requirements
- Relationship between ISO 13485 and general duties of the manufacturer from Art. 10 of EU 2017/745 and EU 2017/ 746 Regulations (tables ZA.1 and ZB.1)
- Relationship between ISO 13485 and requirements referring to the quality management system from Annexes IX and XI concerning conformity assessment from EU 2017/745 and EU 2017/746 Regulations (tables ZA.2, ZA.3, and ZB.2, ZB.3)
- Comparison between ISO 19011:2011 and ISO 19011:2018 requirements
- Audit terms and principles. Types of audit. Audit objectives
- Audit planning. Audit documentation. Audit development
- Check-list for internal audit. Collection and checking of information
- Corrective and preventive actions. Audit report. Audit ending

Certificate-Registration-No.: 15/3331/01/28/24/001

Valid until: 2026-10-05

Certification body for personnel of
TÜV Thüringen e.V.



Jena, 2024-05-02

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of the certification body for personnel of TÜV Thüringen e.V.

Mrs. MARINA VOROBIOVA

born: 1986 -05-06 in: Bahmut, Ucraina

has successfully completed the course

Auditor for Medical Devices cf. ISO 13485

carried out by TÜV Thüringen Karpat S.R.L.

in Bukarest from 2023-10-04 – 2023-10-06

Education contents:

- General view of ISO 13485:2016 and of the Annex A11:2021 requirements
- Relationship between ISO 13485 and general duties of the manufacturer from Art. 10 of EU 2017/745 and EU 2017/ 746 Regulations (tables ZA.1 and ZB.1)
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