Q–Med

CERTIFICATION COMPANY
MEDITEST

The Federal Service for Accreditation (RusAccreditation)
Registration № RA.RU.13ФК27
Q-Med Voluntary Certification System of Management Systems
Registration № РОСС RU.32243.04МДТ0
MEDITEST Management Systems Certification Body
MEDITEST Limited Liability Company
Mnevniki Street, 3, unit 1, Moscow, 123308, Russia

CERTIFICATE OF CONFORMITY

Issue 1

is given to **ICL Tehno Limited Liability Company**
(ICL Tehno LLC)
Sovetskaya str., unit 278, office 18 (1005), Stolbishchenskoe, v. Stolbishche,
Laishevskij district, resp. Tatarstan, 422624, Russian Federation

THIS CERTIFICATE CERTIFIES THAT:

Quality Management System as applied to design, development, production, installation and service of computer and medical equipment. Software and information products of computer equipment and medical equipment, equipment installation services; activities related to the use of computer technology, medical equipment and information technology

COMPLIES WITH THE REQUIREMENTS OF

GOST R ISO 9001–2015 (ISO 9001:2015, IDT) and
GOST ISO 13485–2017 (ISO 13485:2016, IDT)

(Annex specifying the scope of certification is an integral part of this certification)

Registration № RA.RU.13ФК27.К00093

Date of registration 2023, July, 17 **It is valid until** 2026, July, 17

Head of Management Systems Certification Body **L.V. Goryunova**

Audit team leader **S.V. Solonnikov**

Account number 0037

Annex
It is an integral part
of the certificate № RA.RU.13ФК27.К00093
(Sheet 1 of 1)

Quality Management System Certification Scope of ICL Tehno Limited Liability Company

1. **Products and services:**
   Computer and medical equipment, software and information products of computer equipment and medical equipment, equipment installation services; activities related to the use of computer technology, medical equipment and information technology

2. Requirements of GOST ISO 13485-2017 (ISO 13485:2016, IDT) not applicable to the quality management system:

- Conformation control (6.4.2)
- Installation activities (7.5.3)
- Particular requirements for sterile medical devices (7.5.5)
- Particular requirements for validation of processes for sterilization and sterile barrier systems (7.5.7)
- Particular requirements for implantable medical devices (7.5.9.2)
- Customer property (7.5.10)

3. Requirements of GOST R ISO 9001-2015 (ISO 9001:2015, IDT) not applicable to the quality management system:

- Property belonging to customers or external providers (8.5.3)

4. Production sites:

- Sovetskaya str., unit 278, office 18 (1005), Stolbishchenskoe, v. Stolbishche, Laishevskij district, resp. Tatarstan, 422624, Russian Federation
- Dorozhnaya str., 42, v. Usady, Laishevskij district, resp. Tatarstan, 422616, Russian Federation

Chief specialist of Management Systems Certification Body — **L.V. Goryunova**

Audit team leader — **S.V. Solonnikov**

17.07.2023