

Client Name and address



LLC «BACTOSFERA»

8, VACLAV HAVEL BOULEVARD, KYIV, UKRAINE, 03124

Standard

ISO 13485:2016

Medical Devices- Quality Management System

INSPECT has assessed and approved the compliance of the relevant organization with the requirements of the above-mentioned standard within the relevant scope.

Scope

Development, production and sale of electrical appliances for household and medical purposes

IAF/Category Code: Active (Non-Implantable) Medical

Initial issue date: 22.Dec.2022

Issue date of this certificate: 27.Dec.2024

Recertification date: 21.Dec.2025

Certificate No: 20.10.534-MD

The validity period of certificate is 3 years.

INSPECT is accredited by International Accreditation Service (IAS)

To verify the validity of this certificate please visit: www.inspect.com.tr

The validity of this certificate depends on the success of surveillance assessments




General Manager



Client Name and address

**ТОВ «БАКТОСФЕРА»**

Україна, 03124, Київ, бульвар Вацлава Гавела, 8

Standard

ISO 13485:2016

Медичні вироби.
Система управління якістю.
Вимоги до регулювання

INSPECT has assessed and approved the compliance of the relevant organization with the requirements of the above-mentioned standard within the relevant scope.

Scope

Розробка, виробництво і реалізація електроприладів побутового та медичного призначення

IAF/Category Code: Active (Non-Implantable) Medical

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General Manager

