

## 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](http://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

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](http://www.inspect.com.tr)

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



  
General Manager

