EAC

European Assessment and Certification

This Certificate of Conformity has been awarded to

Inferum LLC

Apt. 487, 86, Belinsky St., Ekaterinburg,
Russia, 620026

In recognition of the organization's Quality System that conforms to the requirements of the applicable Harmonized Standards as mentioned in the Annexure under

CE

CONFORMITÈ EUROPËENNE

The quality system has been assessed, approved and is subject to continuous surveillance according to the Council Directive on Medical Devices Regulation (EU) 2017/745 (MDR), Low Voltage Directive 2014/35/EU (LVD), Electromagnetic Compatibility Directive 2014/30/EU (EMC). The Certification Body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified products under Class IIa

Physiotherapeutic device for correction of blood pressure «INFERUM», model ABP-051; model ABP-052
Physiotherapeutic device for reducing blood viscosity «INFERUM», model IBF

Certificate No : CE-9874

Certificate issue date : 19-04-2024
Certificate expiry date : 18-04-2027
1st Surveillance due before : 18-04-2025
2nd Surveillance due before : 18-04-2026

ASIB ACCREDITATION INTERNATIONAL
MSCB155

CE

Authorised Signatory
European Assessment and Certification

European Assessment and Certification

The conformity of the product(s) according to the provisions of MDR is determined by the observance of the following European Standards:

EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 13485:2016	Medical devices - Quality management systems -Requirements for regulatory purposes
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-9:2021	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 10993-13:2010	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices
EN ISO 10993-15:2023	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of materials
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN 62304:2006 / A1:2015	Medical device software - Software life-cycle processes
EN 62366-1:2015 / A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-11:2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

MSCB155

Authorised Signatory
European Assessment and Certification

EAC

European Assessment and Certification

The conformity of the product(s) according to the provisions of LVD is determined by the observance of the following European Standards:

EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
EN 60601-2-10:2015	Medical electrical equipment. Part 2: Particular requirements for the safety of nerve and muscle stimulators
EN 60601-1-6:2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

The conformity of the product(s) according to the provisions of EMC is determined by the observance of the following European Standards:

EN 60601-1-2:2015	Medical Electrical Equipment. Part 1. General requirements for safety. 2 Electromagnetic compatibility – requirements and tests.

ASIB ACCREDITATION INTERNATIONAL
MSCB155

CE

Authorised Signatory
European Assessment and Certification