



EC Certificate – Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)
Certificate No. MDD-009

Issued to: "Vitaфон" Co. Ltd.,
Ogorodnyy pier. 23, 198097 Saint-Petersburg
Russia
Place of production: "Vitaфон" Co. Ltd.,
Ogorodnyy pier. 23, 198097 Saint-Petersburg
Russia
Product category: Active therapeutic device intended to administer or exchange energy
GMDN: 61096

SIQ has audited the quality system in accordance with MDD Annex II excluding (4) and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex II. This certificate is based on

Audit report No.:

OSV 00577/2017, 2017-06-08
OSV 00163/2019, 2019-02-28
OSV 00221/2020, 2020-02-28
OSV 00104/2020, 2020-03-17
OSV 00332/2020, 2020-04-16

See also decision of NB's commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality system is subject to periodical surveillance as referred to in Directive 93/42/EEC concerning medical devices Annex II (5) and continues to meet the above requirements.

Certification date: 2010-12-03

Issue : 06/2020-04-16

Valid until: 2024-05-27



Director of SIQ

Igor Likar