

The management system of

Innomed Medical Zrt.

1146 Budapest, Szabó J. u. 12.
Hungary

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 28 July 2004
and first certified by SGS Belgium NV since 16 December 2019

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered HU/BUD HU0075MYH

Authorised by

SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Innomed Medical Zrt.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

TOP-X range of high frequency X-ray generators and equipments.
HEART-series electrocardiographs.
ARGUSYS 24-hour ECG monitors.
Cardio PC cardiological measuring system.
Cardio Aid cardiac defibrillators (CA360B, CA-1 AED, CA-1 AED PLUS).
Innobase cardiological software systems.
MRX TEL II Remote Controlled X-ray Diagnostic Table.
MRX TEL NG II X-ray system with tomosynthesis function.

TOP-X nagyfrekvenciás röntgengenerátor család és rendszerek.
HEART sorozatú elektrokardiográfok.
ARGUSYS 24-órás EKG monitorok.
Cardio PC kardiológiai mérőrendszer.
Cardio Aid kardiológiai defibrillátorok. (CA360B, CA-1 AED, CA-1 AED PLUS)
Innobase kardiológiai szoftver rendszerek.
MRXTEL II Távvezérelt röntgendiagnosztikai vizsgáló szerkezet
MRXTEL NG II Távvezérelt átvilágító-, és felvételi röntgen rendszer,
digitális tomoszintézis opcióval.

Рентгеновские оборудования и рентгеновские генераторы
высокой частоты «TOP-X».
Электрокардиограф серии«HEART».
Суточные мониторы ЭКГ «ARGUSYS».
Кардиологическая измерительная система «Cardio PC».
Дефибрилляторы«CardioAid (CA360B, CA-1 AED, CA-1 AED PLUS)».
Кардиологические программные системы «Innobase».
Дистанционно управляемый рентгено-диагностический комплекс«MRXTEL II».
Рентгеновская система с функцией томосинтез«MRXTEL NG II».

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

2500 Esztergom, Schweidel u. 50. Hungary