

EC Certificate Full Quality Assurance System: GB98/13599

The management system of

Innomed Medical Zrt.

Szabó J. u. 12.,
Budapest, 1146, 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 10 June 2013 until 9 June 2018 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 10 June 2016
Issue 14. Certified since 28 July 2004

Certification is based on reports numbered HU0075 MYH

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

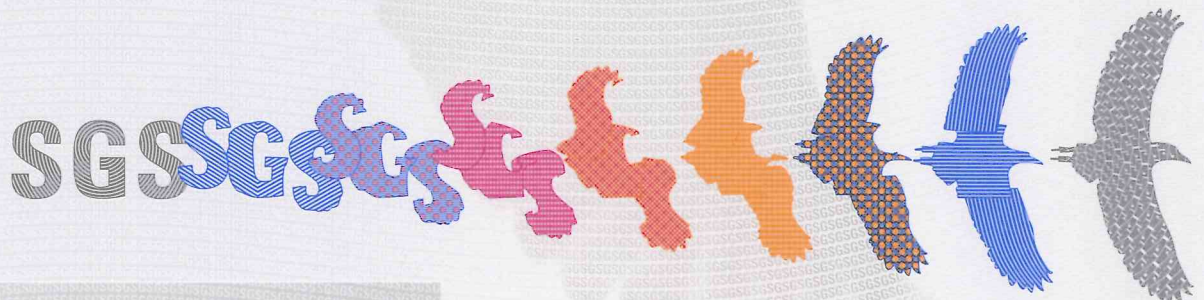
Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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Innomed Medical Zrt.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 14

Detailed scope

TOP-X range of high frequency X-ray generators and equipments.
TOP-X 100MS Mobile X-ray systems
InnoSpot 1000 digital image processor system.
PI-PACS integrated RIS/PACS system.
PI-PACS Chest CAD decision support system for medical use
HEART-series electrocardiographs.
ARGUSYS 24-hour ecg monitors.
INNOCARE patient monitor system.
Cardio PC cardiological measuring system.
Cardio Aid cardiac defibrillators.
Innobase cardiological software systems.

Рентгеновское оборудование и рентгеновские генераторы
высокой частоты «TOP-X»
Аппараты рентгеновские передвижные «TOP-X 100MS»
Цифровая система обработки изображения «InnoSpot 1000».
«PI-PACS» интегрированная система RIS/PACS
Медицинская система поддержки принятия решения «PI-PACS
Chest CAD»
Электрокардиограф серии «HEART».
Суточные мониторы ЭКГ «ARGUSYS».
Система мониторинга пациента «INNOCARE».
Кардиологическая измерительная система «Cardio PC».
Дефибрилляторы «Cardio Aid».
Кардиологические программные системы «Innobase».

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

Additional facilities

H-2500 Esztergom Schweidel u.50. HUNGARY