

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.

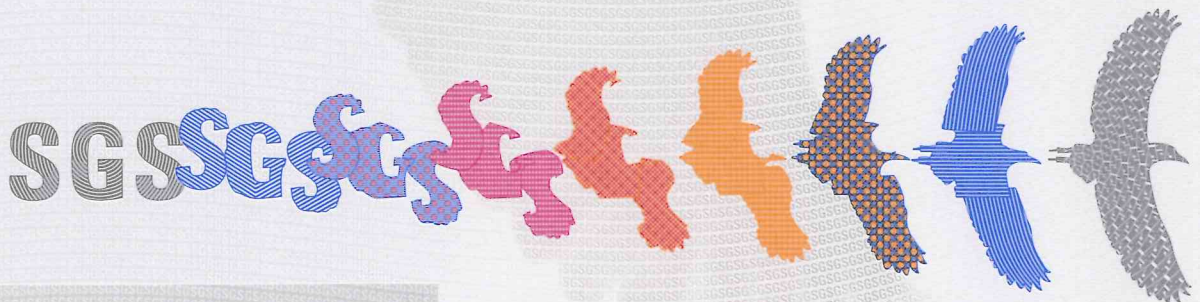
Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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SGS CE 01 0311 M2

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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.

Innibase cardiological software systems.

TOP-X nagyfrekvenciás röntgengenerátor család és rendszerek.

TOP-X 100MS Mobil röntgen rendszerek.

Innospot 1000 digitális képfeldolgozó rendszer.

PI-PACS integrált RIS-PACS rendszer

PI-PACS Chest CAD orvosi döntéstámogató rendszer

HEART sorozatú elektrokardiográfok.

ARGUSYS 24-órás EKG monitorok.

INNOCARE páciens monitorozó rendszer.

Cardio PC kardiológiai mérőrendszer.

Cardio Aid kardiológiai defibrillátorok.

Innibase kardiológiai szoftver rendszerek.

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