



Certificate HU98/13598

The management system of

Innomed Medical Zrt.

1146 Budapest , Szabó J. u. 12. - Hungary

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

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

This certificate is valid from 5 June 2019 until 9 June 2022
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 21 May 2022

Issue 5. Certified since 9 June 1998

This is a multi-site certification.

Additional site details are listed on subsequent pages.

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com



0005

HC SGS 13485 2016 0118 M2

Page 1 of 2



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Innomed Medical Zrt.

ISO 13485:2016 EN ISO 13485:2016



Issue 5

Detailed scope

Design, development, manufacture, servicing, installation and distribution of patient monitoring, diagnostic and therapeutic electromedical devices, X-ray generators and X-ray devices and medical imaging and cardiological software.

Systematic revision and retesting of X-ray medical devices according to 4/2009 (III.17.) EüM Hungarian regulation

Páciens monitorozó, diagnosztikai és terápiás orvostechnikai eszközök, röntgengenerátorok és röntgenteknikai berendezések valamint orvostechnikai képkalkító és kardiológiai szoftverek fejlesztése, gyártása, installálása, javítása és forgalmazása. Röntgenkészülékek időszakos felülvizsgálata a 4/2009 (III.17.) EüM rendelet előírása alapján.

Additional facilities:

2500 Esztergom, Schweidel u. 50. - Hungary



0005