EC Certificate Full Quality Assurance System: Certificate US19/819943475

The management system of

GraMedica

16137 Leone Drive
Macomb, MI, 48042, United States

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

HyProCure Sinus Tarsi Implant system.
Sterile sinus tarsi implants and nonsterile reusable instruments used for the stabilization and/or correction of bones in the foot

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.

This certificate is valid from 16 December 2019 until 04 June 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 03 June 2006
and first certified by SGS Belgium on 16 December 2019

Certification is based on reports numbered WW/MC 214088

Authorised by

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