EC Certificate Full Quality Assurance System: ES13/14384

The management system of

CELSIUS MEDICAL S.L.

Carretera de Torrejón a Ajalvir km 5,2.
28864 Ajalvir, Madrid. Spain

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 19 January 2015 until 9 July 2018
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 5 April 2016
Issue 2. Certified since 9 July 2013

Certification is based on reports numbered ESMAD/101713

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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CELSIUS MEDICAL S.L.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 2

Detailed scope

Medical Fluids Warming System: GEYSER & GEYSER PLUS.
Patient warming device for convective air blankets: CALIMA.
Sterile Single-use Heater exchanger for GEYSER device.

Class I sterile – Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions.
Sterile blanket for CALIMA device.

Sistema de calentamiento de fluidos médicos: GEYSER & GEYSER PLUS
Dispositivo de calentamiento de pacientes mediante mantas de aire de convección: CALIMA.
Intercambiador de calor estéril de un solo uso para equipos GEYSER.

Clase I estéril - Restringido a los aspectos de fabricación relacionados con la seguridad y el mantenimiento de las condiciones estériles.
Cobertura estéril para equipo CALIMA.

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.