

The management system of

Carilex Medical, Inc.

No. 77, Keji 1st Rd., Guishan Township,
Taoyuan County 333, Taiwan, R.O.C.

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

Air flotation mattress for decubitus ulcers (bed sores) treatment.

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.

This certificate is valid from 10 February 2015 until 10 February 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 30 September 2017
Issue 1. Certified since 10 February 2015

Certification is based on reports numbered TW/TPE 606647

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 01 0311

Page 1 of 1

