

EC CERTIFICATE

Certificate No 1744/MDD

Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

GVP MED SAS DI MIAN ANTONELLA & C.

21027 SARONNO (VA) - VIA GALVANI 2 (ITA) - Italy

manages in the factories of:

21042 CARONNO PERTUSELLA (VA) - VIALE EUROPA 1457 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Heating mattress for medical use

Type ref. SCLMED2.0 (VAR100A2011 + SCLD125 + GELMAT3.5); TRMMEDP/S 2.0 (VAR100A2011 + SCLDPS + GELMAT3.5); TRMMEDP/SS 2.0 (VAR100A2011 + SCLDPSS + GELMAT3.5); TRMMEDP2.0 (VAR100A2011 + SCLDP + GELMAT3.5).

Trade mark GVP

Heating blankets for medical use

Type ref. DMEMG2.0 (VAR100A-EMG + SCL-EMG + NL2024HD22 + CAVO DC); SCL K 2.0 (VAR100A-EMG + SCL-EMG + CAVO DC); SCL DC 2.0 (SCL-EMG + CAVO DC); SCL BT 2.0 (SCL-EMG + NL2024HD22 + CAVO DC).

Trade mark GVP

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II.

Reference to IMQ files Nos: 10AO00241.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.
Notified Body notified to European Commission under number: 0051.

Date:

2014-12-16



IMQ

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".
In any case, it does not remain valid after 2019-12-15 (article 11, clause 11 of the Directive).

This is a translation of the Italian text, which prevails in case of doubts