EC CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name	: Hangzhou Zhengda Medical Co. Ltd
Company Address	: 501 No.22 Xingyan Road, Yuhang District Hangzhou, Zhejiang, China
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Non-sterile Electric Tourniquet System - Class IIa Non-sterile Cooling System - Class IIa Non-sterile Compression Therapy System - Class IIa Non-sterile Upper Limb Continuous Passive Motion - Class IIa Non-sterile Lower Limb Continuous Passive Motion - Class IIa Non-sterile Shockwave System - Class IIa Non-sterile Medical Electric Saw &Drill System - Class IIa Non-sterile Massage System - Class IIa Non-sterile Hypo-/hyperthermia System - Class IIa
GMDN	: 14074, 36758, 10969, 17137, 36313, 47995, 37867, 34663, 36956 Product Types are attached.
Certificate Number	: M.2021.106.14217
Report Number	: MD.4048.IB
Initial Assessment Date	: 11.12.2019
Registration Date	: 18.01.2021
Revision Date /No	: -
Expiry Date	: 27.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc.

Digitally signed by Turcanu Ştefan
Date: 2021.12.10 13:47:05 EET
Reason: MoldSign Signature
Location: Moldova

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr