MEDICAL DEVICES CHANGE CONFIRMATION FORM

The validity of the Change Confirmation Form expires when the validity period of related EC Certificate/s expires. The Change Confirmation Form alone has no function.

Company Name : Hpotech Medikal ve Teknik Çözümler Sanayi ve Ticaret Anonim Şirketi

Company Address : Ferhatpaşa Mah. 31. Sk. No:49 Ataşehir İSTANBUL / TURKEY

Related Directive : 93/42/EEC Medical Devices Directive

Definition of Change : Company adress has been changed.

Number of Related Certificate : M.2020.106.14112
Report Number : MD.4113
Issue Date : 24.02.2022
Revision Date : -
Revision Number : 00

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM declares that the mentioned changes have been confirmed as non-significant changes according to MDR Article 120-3 and MDCG 2020-3 with this Change Confirmation Form. This form has been prepared to be shared with authorities or third parties upon request.

UDEM

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@udem.com.tr www.udem.com.tr

EC CERTIFICATE

Full Quality Assurance System

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

Company Name	: Hpotech Medikal Ve Teknik Çözümler San. ve Tic. A.Ş.
Company Address	: Cevizli Mahallesi Coşkunlar Sokak No:16-18 İç Kapı No:17 Maltepe İSTANBUL / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: Hyperbaric Oxygen Therapy System - Class IIb
GMDN	: 12061
Certificate Number	: M.2020.106.14112
Report Number	: MD.4113.IB
Initial Assessment Date	: 17.07.2020
Registration Date	: 14.12.2020
Revision Date /No	: 06.05.2021/01
Expiry Date	: 27.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

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

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