TURKISH STANDARDS INSTITUTION

CERTIFICATE OF FULL QUALITY ASSURANCE MODULE

METUAS MEDİKAL SAĞLIK HİZMETLERİ DANIŞMANLIK İTHALAT İHRACAT A.Ş.
TURAN GÜNEŞ BULVARI NO:75/7 Çankaya/ANKARA/TURKEY

located at the adress

OSTİM MAHELLESİ GÜL86 YAPI KOOP. 1151. SOKAK NO:55 OSTİM YENİMAHALLE ANKARA/TURKEY

for the scope of;

ARTCURE DIFFUSIONAL PATCH

has been examined and certified to the requirements of

93/42/EEC – Medical Device Directive Full Quality Assurance Module – Module H (Annex-II)

by considering the related clauses of TS EN ISO 13485:2012

Notified Body Number:

1783

Certificate Issue Date:

30.09.2013

Valid Until:

30.09.2018

GMDN Code:

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Applied Rule and Classification:

Medical Device Directive Annex IX, Rule 3- Class IIB

Examination Report Number:

511-MDD-006/2013-04

Date / Reason of the Certificate Revision

07.10.2013 / Change in registered head office address

This certificate remarks that quality system meets requirements of the technical regulations / harmonized standards and with this certificate the company is authorized to affix CE Mark, as shown below, and Notified Body Number on the products in the scope of the examined quality system. Notified Body has the right to carry out surveillance visits announced or unannounced in accordance with section 5 of Annex 2 of Medical Device Directive.

CE

Certificate Number: 1783 - MDD - 006

TSE DE LA CONTROL DE LA CONTRO

Sezai DOĞAN TSE Director of Directives ANKARA Rev 01, 07/10/2013