## **CERTIFICATE**

Number: 2161507

The management system of:

#### ALVIMEDICA TIBBI ÜRÜNLER SAN VE DIS TICARET A.S.

Istanbul Trakya Serbest Bölgesi Ferhatpasa Mah. Atatürk Bulv. Manolya Sok.No.7 34540 Çatalca, Istanbul Turkey

including the implementation meets the requirements of the standard:

## EN ISO 13485:2012

Scope:

Design, development, manufacture and distribution of: Disposable single use and implantable medical devices for use in ENT, Oncology Disease Management, Cardiopulmonary Surgery, Cardiology, Radiology and Nephrology.

This certification also includes the location as identified on the addendum belonging to this certificate.

Certificate expiry date: 1 June 2018
Certificate effective date: 19 June 2015
Certified since: 8 July 2013

This certificate is also valid for the organization(s) and/or locations/mentioned/on the addendum.

DEKRA Certification B.V.

drs. G.J. Zoetbrood Managing Director ing. A.A.M. Laan Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



# **ADDENDUM**

To certificate: 2161507

The management system of:

#### ALVIMEDICA TIBBI ÜRÜNLER SAN VE DIS TICARET A.S.

Istanbul Trakya Serbest Bölgesi Ferhatpasa Mah. Atatürk Bulv. Manolya Sok.No.7 34540 Çatalca, Istanbul Turkey

List of certified locations

Location	Scope certificate / Activity
Alvimedica Saglik Ekipmanlari Kazanci Yokusu No. 45 Beyoglu-Istanbul	Sales and marketing of disposable single use and implantable medical devices for use in ENT, Oncology Disease Management, Cardiopulmonary Surgery, Cardiology, Radiology and Nephrology

Initial date: 8 July 2013 Effective date: 19 June 2015