DECLARATION OF CONFORMITY
to
Directive 93/42/EEC concerning Medical Devices

Name of Product: Alvision™ Interventional Cardiology Diagnostic Catheter

Legal (labeled) Manufacturer: Alvimedica Tibbi Ürünler Sanayi ve Diş Ticaret A.Ş.
İstanbul Trakya Serbest Bölgesi Ferhatpaşa Mah. Atatürk Bulvarı Manolya Sk.
No: 7 Çatalca 34540, İstanbul, Turkey

Declaration:

We, the undersigned, hereby declare that the medical device specified in this declaration conforms to the provisions of the *current* European Council (EC) Directive 93/42/EEC of June 14, 1993 concerning Medical Devices and therefore bears the CE mark of conformity on its labelling in combination with the Notified Body Identification number 0344 of DEKRA Certification b.v., Arnhem, The Netherlands.

- Conformity to the applicable Essential Requirements for Safety and Performance per *current* Directive 93/42/EEC, Annex I: "Essential Requirements" has been proven,
- The device classification (i.e. Class III) has been determined per *current* Directive 93/42/EEC, Annex IX: Classification Criteria,
- The appropriate Conformity Assessment module per article 11 of the *current* Directive 93/42/EEC (i.e., Annex II, Section 4) has been followed as indicated on the "EC Design Examination" Certificate (2161507DE03) in combination with this Declaration of Conformity,
- Alvimedica's Quality Management System fulfils the Quality Management System requirements described in the *current* Directive 93/42/EEC (Annex II, excluding Section 4) and EN ISO 13485: 2012 as evidenced by the "CE Marking of Conformity" Certificate (2161507CE02), its accompanying Certification Notice and the Certificate of Registration (2161507). The specified medical device falls within the scope of Alvimedica's Quality Management System as indicated in the Certificates.

GMDN: GMDN Term*: Angiographic Catheter GMDN Code*: 10688
* per GMDN agency database

Valid until: This Declaration of Conformity is valid until June 1, 2018, i.e. the validity date indicated on the "CE Marking of Conformity" Certificate issued by DEKRA.

Reference: RA-DoCa-003 Rev. 015 - Annex to the Declaration of Conformity.

Place of issue: İstanbul, Turkey

Declared by: Nurşen ERİN Date: 2018-08-07

Quality Assurance Manager