

EC Declaration of Conformity

Manufacturer:

VITAL HEALTHCARE SDN.BHD.
Address: Lot 3, Jalan Sultan Mohamed 3,
Bandar Sultan Sulaiman, 42000 Pelabuhan Klang,
Selangor Darul Ehsan, Malaysia

EU Representative:

MT Promedt Consulting GmbH
Address: Altenhofstrasse 80 D-66386 St.
Ingbert, Germany .
Phone:++49-6894-581020
Fax:++49-6894-581021
DIMDI No.: DE/0000040838

We, the manufacturer, herewith declare that the products

Hollow Fiber Dialyzer

(including system components and accessories)

UMDNS-Code: 11-234 ; GMDN-Code:35004

Model codes: DIA13L, DIA15L, DIA17L, DIA19L, DIA21L

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIb according to Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.:HD 600972580001

Issue date: 2015.03.04

Expiry date: 2020.12.25

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: VITAL HEALTHCARE SDN.BHD.

Address: Lot 3, Jalan Sultan Mohamed 3, Bandar Sultan Sulaiman,
42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia

GUANGZHOU 2015-03-19

Place , date

Mu Fangzhen, Management Representative

Legally binding signature, Function