

## EC DECLARATION OF CONFORMITY

The following EC declaration of conformity exemplifies the required content according to Directive 93/42/EEC.

## EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:

VITAL HEALTHCARE SDN. BHD.

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

We declare under our sole responsibility that

the medical device: **Tubing Sets for Hemodialysis**

*UMDNS Code: 11225*

Brand Name: VITAL

Model codes: BLU001E, BLU002E, BLU003E, BLU004E, BLU005E, BLU006E, BLU007E, BLU008E, BLU009E, BLU010E, BLU011E, BLU012E, BLU013E, BLU014E, BLU015E, BLU016E, BLU017E, BLU018E, BLU019E, BL 90, BL 36, BL 009, BL 10, BL 05, BL 008, BL 06, BL 31, BL 14, APBL-013E

of class: IIa

according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure:

**Directive 93/42/EEC Annex II, excluding Section 4**

Registration No.:

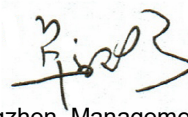
**HD 60139484 0001**

Notified Body:

**TÜV Rheinland LGA Products GmbH  
Tillystraße 2  
90431 Nürnberg  
Deutschland  
CE 0197**

Klang, 30/08/2019

Place, date /



MU Fangzhen, Management Representative

Name and function

Doc: VH3-J-BL-04(E) rev.: A.5 30/08/2019