

## 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: BL 05 R, BL 10 R, BL 10 E2C, BL 24, BL 25, BL 33, BL 36 R, BL 37, BL 38 SN, BL 39, BL 40 SN, BL 41, BL 90 D4, BL 90 D4T, BL 95 SN, BL 102, BL 105, BL 106, BL 120 N, BL 121P HDF, BL 122P, BL 123P SN, BL 148 SN, BL 150 D, BL 207, BL 208, BL 211 SN, BL 224, BL 245, HINT-4DG, HINT-11G, BL 32 R, BL 200 HDF, BLU001G, BLU002G, BLU003G, BLU004G, BLU005G, BLU006G, BLU007G, BLU008G, BLU009G, BLU010G, BLU011G, BLU012G, BLU013G

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.:

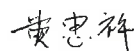
**HD 60139484 0001**

Notified Body:

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

Klang, 06/01/2020

Place, date /



Ng Chong Siong, Management Representative

Name and function

Doc: VH3-J-BL-04(G) rev.: A.6 06/01/2020