

EC DECLARATION OF CONFORMITY

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

Doc: VH3-J-BL-04 (EB) rev.: A.2 30/08/2019

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer:

Vital Healthcare Sdn. Bhd.

Add: 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: BLU001B, BLU002B, BLU003B, BLU004B, BLU005B, BLU006B, BLU007B, BLU008B, BLU009B, BLU010B, BLU011B, BLU012B, BLU013B

of class: IIa

according to Rule 3 in 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.:

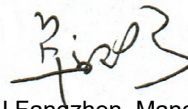
HD 60139484 0001

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

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