

## 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

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

We declare under our sole responsibility that

the medical device: **Hollow Fiber Dialyzers**

UMDNS Code: 11234

GMDN Code: 47072

Brand Name: VITAL

Model codes: V-14LF、V-16LF、V-18LF、V-20LF、V-22LF、V-24LF; V-14HF、V-16HF、V-18HF、V-20HF、V-22HF、V-24HF.

of class: IIb

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.:

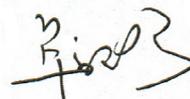
**HD 60139484 0001**

Notified Body:

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

Klang, 30/08/2019

Place, date / Malaysia



MU Fangzhen, Management Representative

Name and function