

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: EKO9030K

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

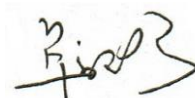
Registration No.:

HD 60139942 0001

Notified Body:

TÜV Rheinland LGA Products GmbH**Tillystraße 2****90431 Nürnberg****Deutschland****CE 0197**Klang, 30/08/2025

Place, date / Malaysia

MU Fangzhen, Management Representative

Name and function