



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: PT 83718, Jalan Bestari 1A/KU7, Taman Perindustrian Kapar Bestari, 42200 Kapar, Selangor, Malaysia.

We declare under our sole responsibility that

the medical device: **Hemodialysis Bicarbonate**

UMDNS Code: 16642

GMDN Code: 35849

Brand Name: VITAL

Model codes: HB001, HB002, HB003, HB004, HB005, HB006, HB007, HB008, HB009

of class: IIb

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**

VITAL HEALTHCARE SDN. BHD.
(COMPANY NO. 1662100-H)

黄忠祥

Klang, 24/03/2023

Place, date

Ng Chong Siong, Management Representative

Name and function