VITAL HEALTHCARE SDN.BHD.
Add: Lot 3, Jalan Sultan Mohamed 3, Bandar Sultan Sulaiman,
42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia

EC DECLARATION OF CONFORMITY

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

Digitally signed by Talpiş Andrei
Date: 2023.03.14 14:58:15 EET
Reason: MoldSign Signature
Location: Moldova

Company No.: 1062100-U Tel : +603-3179 0722 Fax: +603-3179 0822

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

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: Disposable AV Fistula Needle Sets

UMDNS Code: 12741

Brand Name: VITAL
Model codes:

AVF2015SR01E, AVF2015LR01E, AVF2015SR02E, AVF2015LR02E, AVF2015SF01E, AVF2015LF01E,
AVF2015SF02E, AVF2015LF02E, AVF2016SR01E, AVF2016LR01E, AVF2016SR02E, AVF2016LR02E,
AVF2016SF01E, AVF2016LF01E, AVF2016SF02E, AVF2016LF02E, AVF2017SR01E, AVF2017LR01E
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AVF2014SF02E, AVF2014LF02E

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AVF2014SF02AE, AVF2014SR02AE

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AVF3216LF01VE, AVF3216LR01VE, AVF3217LF01VE, AVF3217LR01VE, AVF3215LF01VE, AVF3215LR01VE, AVF3216LF02VE, AVF3216LR02VE, AVF3217LF02VE, AVF3217LR02VE, AVF3215LF02VE, AVF3215LR02VE, AVF3216SF01VE, AVF3216SR01VE, AVF3217SF01VE, AVF3217SR01VE, AVF3215SF01VE, AVF3215SR01VE, AVF3216SF02VE, AVF3216SR02VE, AVF3217SF02VE, AVF3217SR02VE, AVF3215SF02VE, AVF3215SR02VE, AVF3214LF01VE, AVF3214LR01VE, AVF3214LF02VE, AVF3214LR02VE, AVF3214SF01VE, AVF3214SR01VE, AVF3214SF02VE, AVF3214SR02VE

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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. 1062100-U)

黃忠雄

Klang, 05/06/2020
Place, date /

Ng Chong Siong, Management Representative
Name and function

Company No.: 1062100-U Tel : +603-3179 0722 Fax: +603-3179 0822