



WELLMED International Industries Pvt. Ltd.

712, Arunachal Building, 19 Barakhamba Road, New Delhi - 110 001(India)

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DECLARATION OF CONFORMITY

Name and address of product owner:

WELLMED INTERNATIONAL INDUSTRIES PVT.LTD

A-176&177, Sector -63, Noida-201301, U.P., India

We hereby, declare that the below mentioned products meet the provisions of the following EC council directives and standards. All the supporting documentations are retains under the premises of the manufacture.

We hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the essential principles for safety and performance as laid out in the decree on medical equipment management of Vietnam.

Manufacturing site:

WELLMED INTERNATIONAL INDUSTRIES PVT.LTD

A-176&177, Sector -63, Noida-201301, U.P., India

Medical Devices:

No	Product name medical Devices	Model / Brand name	Size
1	Thoracic Drainage catheter	Straight	FG-08,FG-10,FG-12,FG-14,FG-16,FG-18,FG-20,FG-22,FG-24,FG-26,FG-28,FG-30,FG-32,FG-34,FG-36,FG-38,FG-40.
2	Thoracic Drainage catheter	Curved	FG-08,FG-10,FG-12,FG-14,FG-16,FG-18,FG-20,FG-22,FG-24,FG-26,FG-28,FG-30,FG-32,FG-34,FG-36,FG-38,FG-40.
3	Thoracic Drainage catheter with trocar		FG-08,FG-10,FG-12,FG-14,FG-16,FG-18,FG-20,FG-22,FG-24,FG-26,FG-28,FG-30,FG-32,FG-34,FG-36,FG-38,FG-40.
4	Closed wound drainage set		FG-06,FG-08,FG-10,FG-12,FG-14,FG-16,FG-18.
5	A V Fistula needle with or without back eye rotating or fixed		14G,15G,16G,17G,18G

* **List of standard applied:** EN ISO 13485:2003/EN ISO 13485:2012/ISO 9001:2008

Medical devices-Quality management systems requirements for regulatory purposes (EN ISO 13485:2003/EN ISO 13485:2012/ISO 9001:2008); Certificate No : 247997-2017-AQ-IND-NA-PS Rev. 0.0

This declaration of conformity is valid form 12 Oct, 2017 to 31 Jan, 2020

Authorized Signatory

Date: 12 Oct, 2017



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