



Harsoria Healthcare Pvt. Ltd.

(A 100% Export Oriented Unit)

110-111, Phase-IV, Udyog Vihar, Gurgaon, Haryana - 122015, INDIA

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EC Declaration of Conformity

We **HARSORIA HEALTHCARE PVT. LTD.,**
Plot 110-111, Phase-IV, Udyog Vihar, Gurgaon, Haryana-122015,
India.

Declare with sole responsibility, that our product/s:

| MEDICAL DEVICES | GMDN | UMDN | MD CODE | CLASSIFICATION-RULES |
|---|-------|--------|---------|----------------------|
| I.V. Cannula with Catheter with or without Injection Valve and with or without wings. (12-26G) | 40601 | 10-727 | 0102 | Class IIa-7 |
| Safety I.V. Cannula with Catheter with or without Injection Valve and with or without wings. (14-26G) | 40601 | 10-727 | 0102 | Class IIa-7 |
| A. V. Fistula Needle Set | 12741 | 18-245 | 0102 | Class IIa-7 |
| Injection Stopper | 16858 | 16-858 | 0102 | Class IIa-2 |
| 3 Way Stop Cock | 32172 | 13-803 | 0102 | Class IIa-2 |
| 3 Way Stop Cock with Extension Tube | 32172 | 12-170 | 0102 | Class IIa-2 |
| Extension Tube | 36244 | 12-170 | 0102 | Class IIa-2 |
| Flow Regulator Set | 16789 | 16-789 | 0104 | Class IIa-2 |
| Luer Cap | 61141 | 16-081 | 0102 | Class IIa-2 |
| Combi Luer Lock | 35075 | 16-851 | 0102 | Class IIa-2 |

Details of Samples

SAMPLE:

| S.NO | PRODUCT NAME | LOT NO / CYCLE NO. | D / MFG | D / EXP | SAMPLE QTY |
|------|--------------|--------------------|---------|---------|------------|
| 1. | | | | | |

List Of Applicable Standards, Related to Product (ANNEXURE-I)

Are in conformity with the essential requirement and provisions of the Council Directive MDD/ 93/42/EEC & are subject to the procedure set out in Annexure-2 (excluding point 4) of directive MDD/ 93/42/EEC amended by Directive 2007/47/EEC under the supervision of the Notified Body.

Notified Body's Name - DNV GL Presafe AS

Notified Body's Address - DNV GL Presafe AS-Veritasveien 3, N-1363 Hovik, Norway.

CE Mark - CE 2460

Certification No.: - 11168-2017-CE-IND-NA-PS REV. 1.0

Issuing Date - 14 July 2020

Valid Up to - 27 May 2024

The above products meet the essential requirements of EITHER council Directive MDD/93/42/EEC amended by Directive 2007/47/EEC Pertaining to medical devices.

We hereby appoint **mdi Europa GmbH**, Langenhagener Str. 71, 30855 Hanover-Langenhagen, Germany to act as European Authorized Representative.

Signed this day 14/07/2020

