



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

