Harsoria	FORMAT	Doc. No.:	F/QA/40-00
	DECLARATION OF CONFORMITY	Supersedes:	None
		Report Date:	14/03/2024
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Manufacturers Name:	HARSORIA HEALTHCARE PVT. LTD
Manufacturers Address:	Legal Manufacturer Harsoria Healthcare Pvt. Ltd. Plot 110-111, Phase-IV, Udyog Vihar, Gurgaon, Haryana-122015, India. Productions site /factory Unit 2 Harsoria Healthcare Pvt. Ltd. KK83/85, Kh No.342/266 Saraj majra Gujran, Baddi-Jharmajri Road, Distt. Solan, Himachal Pradesh, Baddi-173205, India.
Contact Details	Tel.: +91-124-4523400
SRN (Single Registration Number):	IN-MF-000018349
Authorized Representative Name & Address:	mdi Europa GmbH Langenhagener Str. 71, D-30855 Langenhagen, Germany
Authorized Representative SRN:	DE-AR-000006218
Basic UDI-DI:	89043991HSETP013Z
Product Name	Three way stop cock with Extension tube
Product Variant	Three way stop cock / Three way stop cock with Extension tube

Product Reference	Product Code	Catalogue No.	Product Description	Batch No.	D / Mfg.	D / Exp.
	-	-	-	-	-	-

Technical File Document No.:	HHPL-D&D-TF-3WSC
Device Trade Name:	-
Intended Purpose:	3 Way Stop Cock is an auxillary product that is used in conjuction with some other product for administration of fluid or sampling of blood during infusion therapy.
EMDN Code:	A0703
MDR Codes:	MDN 1202, MDS 1005, MDT 2002, MDT 2008, MDT 2011
Classification/Rule	It is an IIa device and Rule 2 as per Annex VIII of MDR 2017/745
Harmonized Standards applied	Ref. Document No.: HHPL-D&D-LAS-3WSC
Conformity assessment route:	Annex IX, Chapter I & III
Notified Body Name	TUV SUD Product Service GmbH.
Notified Body Number	CE 0123
Notified Body Address	Ridlerstraße 65· 80339 Munich· Germany
EC Certificate Number	G10 107353 0004 Rev. 00
Valid till	2029-03-12

This declaration of conformity is issued under the sole responsibility of Harsoria Healthcare Pvt. Ltd. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485:2016 All supporting documentation is retained at the premises of the manufacturer.

Signature:

QA

Name: Amod Kumar
Designation: Person responsible for Regulatory compliance

Place and date of issue: Gurugram,
Date. 17.05.2024