



EU Declaration of Conformity

Manufacturer Details : TULIP DIAGNOSTICS (P). LTD
Dukle Heaven, Block III, 301 & 401, St. Inez,
Taleigao Road, Taleigao, Tiswadi, North Goa
Goa - 403 002, India.
Tel.: +91 7066031234/35/36
Email: tulipiau1@gmail.com
Website: www.tulipgroup.com
Single Registration Number (SRN): IN-MF-000013853

Details of Person responsible for regulatory compliance (PRRC) : Udhalak Naik
Manager - Quality Management System

Details of Authorized Representative : CMC Medical Devices & Drugs S.L.
C/Horacio Lengo N°18
CP 29006, Malaga, Spain.
SRN : ES-AR-000000293

Contact Details : Mr. Manuel Mateos
Tel : +34951214054
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Email : mmateos@cmcmmedicaldevices.com
Web : www.cmcmmedicaldevices.com

Basic UDI-DI: 8903272IDVS01WW

Product Details:

Generic Name : The Hand-Held Vein Finding Device

Trade / Brand Name : VeinSpy™

Catalogue Number : 825VS000000

European Medical Device Nomenclature (EMDN): V9099

Intended Purpose: **VeinSpy™** is a wireless, hand-held portable vein finding device based on the principle of "**Transverse illumination Technology**" for the visualization of superficial & deep veins.

Classification : Class I, Rule 13

Details of Notified body:

Name : -

Address : -

Identification number : -

The CE certificate number : -

Conformity Assessment Route: According to the Regulation (EU) 2017/745 Annex IV.

DOC/VS/01

Corporate Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.
Tel.: (0832) 2458546-51, Fax: (0832) 2458544. E-mail: sales@tulipgroup.com, Website: www.tulipgroup.com



This declaration of conformity is issued under the sole responsibility of Tulip Diagnostics (P). LTD. We herewith declare that the above mentioned product meet the transposition into national law, the provisions of the following EU Council directives/regulations and Standards. This declaration is supported by the Quality System approval to ISO 13485:2016 issued by Zenith Quality Assessors.

All supporting documentations are retained under the premises of the manufacturer.

General applicable directives / regulations: Regulation (EU) 2017/745 Annex IV.

Standards Applied: ISO 13485:2016, EN ISO 14971:2019, ISO-TR 24971:2020,
EN ISO 15223-1:2016, EN 60601-1-2:2007, CEN ISO/TR 24971:2020

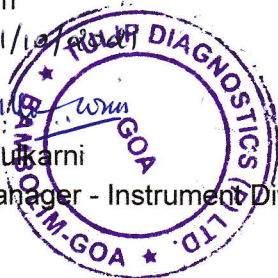
Place: Bambolim

Date of issue: 11/10/2021

Signature:

Name: Satish Kulkarni

Designation: Manager - Instrument Division



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