Declaration of Conformity

Manufacturer Name & Address:
TULIP DIAGNOSTICS (P).LTD
Gitanjali Tulip Block, Dr.Antonio Do Rego Bagh,
Alto Santa Cruz, Bambolim Complex Post Office,
Goa-403202, INDIA

European Representative Name and Address:
CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo No.18
CP 29006, Malaga, Spain.

Product Name: Vein Finder

Model: VeinSpy ™

Catalogue number: 825VS000000

Classification: Class 1, Rule 2 Devices of MDD 93/42/EEC as amended by 2007/47 (Medical Devices)

Conformity Assessment Route: MDD 93/42/EEC Annex V- Production Quality Assurance

We here with declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council directives and standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives: DIRECTIVE 93/42/EEC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 October 1998 on Medical Devices.

Standards Applied:

EN ISO 13485:2016, EN ISO 14971:2012, EN 1041:2008, ISO 15223-1:2016, EN 60601-1-2:2007

(EC) Certificate(s): 2P201120.TDSW99

Expiry date of the Certificate: 19 November 2023

Start of CE Marking: 20 November 2020

TULIP DIAGNOSTICS (P) LTD. GOA BAMBOLIM

Signature:

Name: Satish Kulkarni

Position: Manager - Instrument Division