

# Certificate of Compliance



No. 2P151126.TDQD58  
 Technical Construction File no. Ver. 1.0/06-J-15

Certificate's  
 Holder:

Tulip Diagnostics (P). Ltd.  
 Dukle Heaven, Block III, 301 & 401, St-Inez, Taleigao  
 Road, Taleigao, Tiswadi, North Goa – 403002, INDIA.

Certification ECM  
 Mark:



Product:  
 Model(s):

VeinSpy™  
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Verification to:

Standard:  
 ISO 9001:2008, EN ISO 13485:2012,  
 EN ISO 14971:2012, EN 980:2008,  
 EN 1041:2008, EN 60601-1-2:2007

related to CE Directive(s):  
 93/42 EEC as amended by 2007/47 EC  
 (Medical Devices) CLASS I, RULE 2,  
 ANNEX V – PRODUCTION QUALITY ASSURANCE

**Remark:** The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Certification Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. Regulation can be found at [www.entecerma.it](http://www.entecerma.it).

Whereas the Manufacturer is responsible of the CE certification of the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market.

The Manufacturer is also responsible to maintain efficient the internal production control to ensure the product(s) are in compliance with the Certification ECM Mark.

This certificate can be checked for validity at [www.entecerma.it](http://www.entecerma.it)

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Expiry date 25 November 2020

Chief Manager  
 Tim Mahan



Deputy Manager  
 Viola Miller



Ente Certificazione Macchine Srl

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