

DECLARATION OF CONFORMITY



SCARLETRED Holding GmbH

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Product Details

Product name	Scarletred®Vision
Product description	Mobile Skin Imaging & Information System
Type	SCR001
System components	Scarletred®Cloud-Platform (#SCR001-101) Scarletred®Mobile-App (#SCR001-201) Scarletred®Skin-Marker (SCR001-301M/L)
Classification according 93/42/EEC, annex IX	Scarletred®Cloud-Platform: Class 1 according to rule 12 Scarletred®Mobile-App: Class 1 according to rule 12 Scarletred®Skin-Marker: Class 1 according to rule 1

Used Standards

Harmonized standards	EN 980:2008 EN 1041:2008 EN ISO 14971:2012 IEC 62304:2006 EN 62366:2008
Other standards	ISO 15223-1:2012 ICH-GCP-Guideline E6 (ISO-GCP)

SCARLETRED Holding GmbH declares under sole responsibility that the products described above as delivered are in compliance with directive 93/42/EEC and the Austrian medical-device-law BGBl. 657/1996.

The products are CE marked.



Vienna, 27. Nov. 2015

Ort, Datum / Location, Date

Mag. Dr. Harald Schnidar MBA
CEO, SCARLETRED Holding GmbH