EC Declaration of Conformity

CT SHIELD

Manufacturer:
Kiran Medical Systems
A Division of Trivitron Healthcare Private Limited
D-117, 134, T.T.C Industrial Area, Shirvane
P.O. Nerul, Navi Mumbai 400 706, India

European Representative:
Mdi Europa GmbH
Langenhagener Str. 71
D-30855 Langenhagen, Germany

Classification: Class I as per rule 1 of Annexure IX, MDD 93/42/EEC as amended by 2007/47/EC

Conformity Assessement Route: Annexure VII , MDD 93/42/EEC as amended by 2007/47/EC

We (KIRAN) hereby declare that the medical device **CT Shield** complies with the medical device directive 93/42/EEC (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) using Annexure VII , MDD 93/42/EEC as amended by 2007/47/EC as the conformity assessment procedure.

It is also in conformity with the provisions of **Regulation EU 2016/425** and, where such is the case, with the national standard transposing harmonized standard No **EN 61331-3:2014, EN 61331-1:2014**

is identical to PPE which is the subject of **EC-Type Examination Certificates** No.GB14/90586 issued by SGS United Kingdom, 202B Worley Parkway, Western-Super-Mare, BS 22, 6WA, **Notified Body Number – 0120.**

is subject to the procedure set out in **Module D of the Directive Regulation EU 2016/ 425** under the supervision of the notified body SGS United Kingdom, 202B Worley Parkway, Western-Super-Mare, BS 22, 6WA, **Notified Body Number – 0120.**

Certificate of **CE marking IN09/78094** is valid until 23rd July, 2021

A Quality Management System based on **ISO 13485: 2003**(Certificate no.IN10/81311 valid from 22 December 2016 to 31 March 2019) has been implemented towards production & quality assurance

Place, Date of issue: Navi Mumbai, India Jan 23, 2019

Sanjay Terse
General Manager – Quality Assurance & Regulatory Affairs

Kiran Medical Systems
A Division of Trivitron Healthcare Private Limited.