

Certificate ES12/00750

The management system of

STEPHANIX S.A.S.

10 Rue Jean Moulin, Z.I. du Bayon, 42150 La Ricamarie, France

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, manufacturing, sales, installation and Technical Service of X-ray medical devices and associated software.

Distribution and installation and Technical Service of imaging medical devices and associated software.

Conception, fabrication, vente, installation et maintenance de dispositifs médicaux de radiologie et des logiciels associés.

Distribution, installation et maintenance de dispositifs d'imagerie médicale et des logiciels associés.

This certificate is valid from 11 February 2025 until 11 February 2028 and remains valid subject to satisfactory surveillance audits.

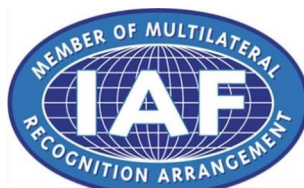
Issue 13. Certified since 25 January 2012

L. Moran

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