

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 12 February 2021 until 11 February 2025 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date Issue 12. Certified since 25 January 2012

Authorised by

HC.

SGS United Kingdom Ltd
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