



Certificate ES12/00750

The management system of

STEPHANIX s.a.

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 2019 until 11 February 2022 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 16 January 2022

Issue 10. Certified since 25 January 2012

Authorised by

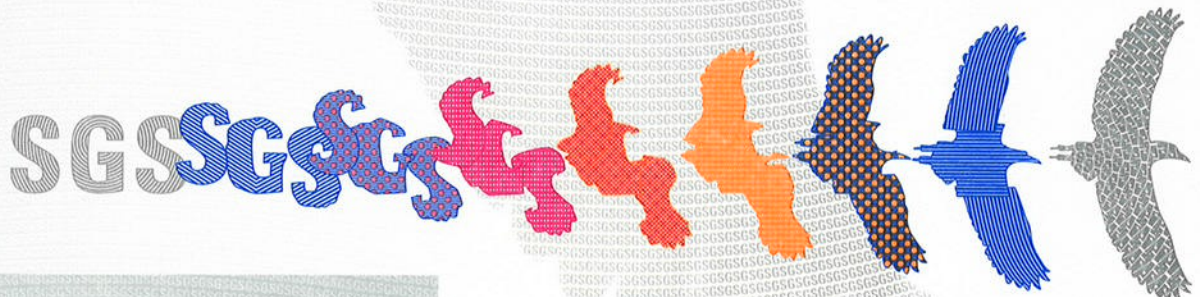
SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

Page 1 of 1



0005



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.