Certificate ES19/86286

The quality management system of

STEPHANIX S.A.S.

10 Rue Jean Moulin, Z.I. du Bayon, 42150 La Ricamarie, France
Facility number: F003898

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Canada: Medical Device Regulations SOR/98-282, Part 1 - General
USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities
Design, manufacturing, installation and service of X-ray medical devices and associated software for the area of Radiology

This certificate is valid from Effective date 2025-02-11 until Expiry date 2028-02-11 and remains valid subject to satisfactory surveillance audits.
Issue 6. Certified since 2019-07-25

L. Henderson

Authorised by

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

SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.