

EC Certificate Full Quality Assurance System: Certificate/Certificat CE Système
complet d'assurance de qualité : FR20/81843524

The management system of / Le système de management de

X-OS s.a.

Boulevard de Pérolle 7, 1700 Fribourg, Switzerland

has been assessed and certified as meeting the requirements of / a été audité et certifié selon les exigences de

Directive 93/42/EEC
on medical devices, Annex II (excluding Section 4)
relative aux dispositifs médicaux, Annexe II (§4 exclu)

For the following products / Pour les produits suivants

**The scope of registration appears on page 2 of this certificate.
Le domaine de certification apparaît en page 2 de ce certificat.**

This certificate is valid from 17 November 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 07 January 2009
and first certified by SGS Belgium NV since 16 December 2019

Ce certificat est valable du 17 novembre 2020 au 24 mai 2024
et reste valide sous condition d'audits de surveillance satisfaisants.
Version 3. Certifié depuis 07 janvier 2009
et initialement certifié par SGS Belgium NV depuis 16 décembre 2019

Certification is based on reports numbered / La certification est basée sur les rapports référence FR/MD 215816

Authorised by / Autorisé par

SGS Belgium NV, Notified Body 1639

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EC Certificate Full Quality Assurance System: Certificate/Certificat CE Système complet
d'assurance de qualité : FR20/81843524 continued

X-OS s.a.

Directive 93/42/EEC
on medical devices, Annex II (excluding Section 4)
relative aux dispositifs médicaux, Annexe II (§4 exclu)

Issue/ Version 3

For the following products / Pour les produits suivants

**Sterile and non-sterile, intramedullary nails, and screws.
Non-sterile drill bits
Non-sterile instrumentation**

**clous centromédullaires et vis, stériles et non stériles.
Forets non stérile et instrumentation de pose non stérile**

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Lorsque le champ d'application ci-dessus comprend un ou plusieurs dispositifs médicaux de classe III, un certificat EC Design Examination Certificate valide, conformément à l'annexe II (section 4), est obligatoire pour chaque dispositif, en addition du présent certificat, pour la mise sur le marché du dispositif.