# CERTIFICAT

*CERTIFICATE OF REGISTRATION*

**N° 28733 rev. 4**

**GMED certifie que le système de management de la qualité développé par**

*GMED certifies that the quality management system developed by*

**Stryker Spine**

**2 Pearl Court,**

**ALLENDALE, NJ 07401 UNITED STATES**

**pour les activités**

*for the activities*

**Conception et fabrication d'implants rachidiens et leurs instruments, de substituts osseux et système de pose, de matériaux d'augmentation osseuse et système de pose, d'aiguilles et seringues de prélèvement de moelle osseuse.**

*Design and manufacturing of spine implants and instruments, bone graft substitutes and delivery devices, bone augmentation materials and delivery devices, bone marrow aspiration needles and syringes.*

**réalisées sur le(s) site(s) de**

*performed on the location(s) of*

**Stryker Spine**
**2 Pearl Court Allendale, NJ 07401 USA**
**Stryker Spine**
**59 Route 17 South Allendale, NJ 07401 USA**

**est conforme aux exigences des normes internationales**

*complies with the requirements of the international standards*

## NF EN ISO 13485:2016

**Début de validité** */ Effective date :* **August 11th, 2021 (included)**
**Valable jusqu'au** */ Expiry date :* **September 30th, 2024 (included)**
**Etabli le** */ Issued on :* **August 11th, 2021**

GMED SAS GMED GROUPE LNE GMED SAS

DocuSigned by: Beatrice Lys EF33BDA9BAA04A3...

**On behalf of the President**
**Béatrice LYS**
**Technical Director**

cofrac CERTIFICATION DE SYSTEMES DE MANAGEMENT
Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED N° 28733–4
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 28733-3

GMED_SQ-F-V0-07-2018

## Ce certificat couvre les activités et les sites suivants :

*This certificate covers the following activities and sites:*

**Conception et fabrication d'implants rachidiens et leurs instruments, de substituts osseux et système de pose, de matériaux d'augmentation osseuse et système de pose, d'aiguilles et seringues de prélèvement de moelle osseuse.**

*Design and manufacturing of spine implants and instruments, bone graft substitutes and delivery devices, bone augmentation materials and delivery devices, bone marrow aspiration needles and syringes.*

**Stryker Spine**

2 Pearl Court
Allendale, NJ 07401
USA

**Stryker Spine**

59 Route 17 South
Allendale, NJ 07401
USA

**********

**2 sites** */ 2 sites*

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

**On behalf of the President**
**Béatrice LYS**
**Technical Director**

**Délivré à Paris le 11/08/2021**
*Issued in Paris on 08/11/2021*

**Ce document complémentaire GMED n° 38347 rev. 3 atteste de la validité du certificat CE n° 25232 rev. 11 au regard des informations listées ci-dessous.**

*This GMED additional document N° 38347 rev. 3 attests to the validity of CE certificate n° 25232 rev. 11 with regard to the information listed below.*

**Fabricant** / *Manufacturer:*

**Stryker Spine**
**2 Pearl Court**
**Allendale, NJ 07401**

## Identification des dispositifs / *Identification of devices*

| **Désignation du dispositif / Accessories marqués CE** *Device designation / EC marked accessories* | **Réf commerciale du dispositif ou code article** *Device commercial reference or article code* | **Classe du DM** *MD Class* |
|---|---|---|
| General Internal Orthopedic Instruments | Radius<br>XIA<br>XIA II<br>XIA 3 (which includes XIA 3 Serrato)<br>XIA 4.5 (which includes XIA CT)<br>Mantis<br>Reflex Hybrid<br>Oasys<br>AVS<br>OIC<br>SOLIS<br>LITe Decompression<br>Reliance<br>Reliance Lite<br>ES2<br>Reliance AL<br>Navigated XIA3 (which includes XIA 3 Serrato)<br>Navigated Mantis<br>Navigation Enable Instruments | Im |

**GMED 0459**

GMED - 38347 rev. 3
Modifie le document no. 38347 rev. 2

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

**On behalf of the President**
**Béatrice LYS**
**Technical Director**

**Délivré à Paris le 11/08/2021**
*Issued in Paris on 08/11/2021*

## **Sites couverts et Activités** / *Locations and Activities*

| **Sites** / *Locations* | **Activités** / *Activities* |
|---|---|
| **Stryker Spine**<br>*2 Pearl Court*<br>*Allendale, NJ 07401*<br>*United States* | **Conception, fabrication, contrôle final**<br>*Design, manufacturing, final control* |
| **Stryker Spine**<br>*59 Route 17 South*<br>*Allendale, NJ 07401*<br>*United States* | **Conception, fabrication, contrôle final**<br>*Design, manufacturing, final control* |

## **Modifications** / *Modifications*

**Identification des modifications apportées au certificat CE n° 25232 rev. 11:**
*Identification of the modifications made to the CE certificate n° 25232 rev. 11:*

| **Modifications** / *Modifications* | **Dossier(s)** / *File(s)* **N°** | **Date** / *Date* |
|---|---|---|
| **Mise à jour de la liste des références** / *Update of list of references* | *T001271-P2-DOCA* | **26 mai 2021**<br>*May 26, 2021* |
| **Nouvelle référence de rapport dans le cadre du maintien de la certification** /<br>*New file reference in the framework of the maintenance of the certification* | *T001271-P1-R* | **11 août 2021**<br>*August 11, 2021* |

**GMED 0459**

GMED - 38347 rev. 3
Modifie le document no. 38347 rev. 2

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

**On behalf of the President**
**Béatrice LYS**
**Technical Director**

**Délivré à Paris le 04/08/2021**
*Issued in Paris on 08/04/2021*

**Ce document complémentaire GMED n° 38346 rev. 1 atteste de la validité du certificat CE n° 26013 rev. 5 au regard des informations listées ci-dessous.**

*This GMED additional document N° 38346 rev. 1 attests to the validity of CE certificate n° 26013 rev. 5 with regard to the information listed below.*

**Fabricant** / *Manufacturer:*

**Stryker Spine**
**2 Pearl Court**
**Allendale, NJ 07401**

## **Identification des dispositifs** / *Identification of devices*

| **Désignation du dispositif / Accessories marqués CE**<br>*Device designation / EC marked accessories* | **Réf commerciale du dispositif ou code article**<br>*Device commercial reference or article code* | **Classe du DM**<br>*MD Class* |
|---|---|---|
| Instruments: general internal orthopedic fixation system implantation kit | LITe Decompression | Is |

**GMED 0459**

GMED - 38346 rev. 1
Modifie le document no. 38346 rev. 0

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

**On behalf of the President**
**Béatrice LYS**
**Technical Director**

## **Sites couverts et Activités** / *Locations and Activities*

| **Sites** / *Locations* | **Activités** / *Activities* |
|---|---|
| **Stryker Spine**<br>*2 Pearl Court*<br>*Allendale, NJ 07401*<br>*United States* | **Conception, fabrication, contrôle final**<br>*Design, manufacturing, final control* |
| **Stryker Spine**<br>*59 Route 17 South*<br>*Allendale, NJ 07401*<br>*United States* | **Conception, fabrication, contrôle final**<br>*Design, manufacturing, final control* |

## **Modifications** / *Modifications*

**Identification des modifications apportées au certificat CE n° 26013 rev. 5:**
*Identification of the modifications made to the CE certificate n° 26013 rev. 5:*

| **Modifications** / *Modifications* | **Dossier(s)** / *File(s)* **N°** | **Date** / *Date* |
|---|---|---|
| **Nouvelle référence de rapport dans le cadre du maintien de la certification** /<br>*New file reference in the framework of the maintenance of the certification* | *T001271-P1-R* | **4 août 2021**<br>*August 4, 2021* |

**GMED** | **0459**

GMED - 38346 rev. 1
Modifie le document no. 38346 rev. 0

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

**On behalf of the President**
**Béatrice LYS**
**Technical Director**

**Délivré à Paris le 04/08/2021**
*Issued in Paris on 08/04/2021*

**Ce document complémentaire GMED n° 38308 rev. 2 atteste de la validité du certificat CE n° 25231 rev. 12 au regard des informations listées ci-dessous.**

*This GMED additional document N° 38308 rev. 2 attests to the validity of CE certificate n° 25231 rev. 12 with regard to the information listed below.*

**Fabricant** / *Manufacturer:*

**STRYKER SPINE**
**2 Pearl Court**
**Allendale, NJ 07401 United States**

## Identification des dispositifs / *Identification of devices*

| **Désignation du dispositlf / Accessories marqués CE**<br>*Device designation / EC marked accessories* | **Réf commerciale du dispositif ou code article**<br>*Device commercial reference or article code* | **Classe du DM**<br>*MD Class* |
|---|---|---|
| Anterior Cervical Plating Systems (ACP) Implants: Cervical Plates, bone screws | Reflex Hybrid<br>Aviator | IIb |
| Posterior Cervical Plating Systems Implants: Occipital, cervical, thoracic plates, screws, hooks, rods and connectors | Oasys | IIb |
| Thoracolumbar (TL) Implants | Diapason<br>Radius<br>XIA (includes XIA Growth Rod conversion set)<br>XIA II<br>XIA 3 (which includes XIA 3 – Serrato)<br>XIA 4.5 (which includes XIA CT implant)<br>Trio / Trio +<br>Mantis<br>Mantis Redux<br>ES2<br>XIA® Precision<br>ES2 Augmentable Implants | IIb |
| Vertebral Body Replacement (VBR) Implants: cages, endocaps | V-LIFT<br>V-LIFT-s | IIb |

**GMED 0459**

GMED - 38308 rev. 2
Modifie le document no. 38308 rev. 1

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

**On behalf of the President**
**Béatrice LYS**
**Technical Director**

**Délivré à Paris le 04/08/2021**
*Issued in Paris on 08/04/2021*

| **Désignation du dispositif / Accessories marqués CE**<br>*Device designation / EC marked accessories* | **Réf commerciale du dispositif ou code article**<br>*Device commercial reference or article code* | **Classe du DM**<br>*MD Class* |
|---|---|---|
| Interbody Fusion and Standalone Implants: cage, plate, vertebral spacers, screws, plates, frame | OIC<br>SOLIS AS<br>AVS AL<br>AVS NAVIGATOR<br>AVS Aria<br>SOLIS<br>AVS TL<br>AVS Anchor-C<br>AVS Anchor-L<br>Tritanium PL<br>Tritanium C<br>Tritanium TL | IIb |
| Spinous Process Fixation System Implants | UniVise | IIb |
| Non-cervical plate implants | Lite® Plate System | IIb |
| Instruments - General internal orthopedic fixation system implantation kit | XIA® 4.5 (which include XIA® CT)<br>XIA® Precision<br>XIA® III<br>Mantis® Augmentable<br>Aviator<br>Oasys<br>ARIA<br>ES2 Augmentable Instruments<br>LITe™ Bio Delivery System<br>LITe™ Y-wire<br>LITe™ Y- needle<br>AERO-C<br>Aero-LL<br>Aero-AL<br>AVS NAVIGATOR<br>AVS<br>AVS ALign<br>AVS Anchor-C Cervical Cage System<br>AVS Anchor-L Lumbar Cage System<br>DYNATRAN<br>ES2 SPINAL SYSTEM<br>LITe PEDICAL BASED RETRACTOR<br>LITe DECOMPRESSION<br>MANTIS Redux<br>RADIUS<br>REFLEX HYBRID<br>RELIANCE | IIa |

| GMED | 0459 |
|---|---|

GMED - 38308 rev. 2
Modifie le document no. 38308 rev. 1

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

**On behalf of the President**
**Béatrice LYS**
**Technical Director**

| **Désignation du dispositif / Accessories marqués CE**<br>*Device designation / EC marked accessories* | **Réf commerciale du dispositif ou code article**<br>*Device commercial reference or article code* | **Classe du DM**<br>*MD Class* |
|---|---|---|
| Instruments - General internal orthopedic fixation system implantation kit | RELIANCE AL<br>RELIANCE C<br>SOLIS<br>Tritanium C<br>Tritanium TL<br>UniVise<br>XIA II | IIa |

## **Sites couverts et Activités** / *Locations and Activities*

| **Sites** / *Locations* | **Activités** / *Activities* |
|---|---|
| **Stryker Spine**<br>*2 Pearl Court*<br>*Allendale, NJ 07401*<br>*United States* | **Conception, fabrication, contrôle final**<br>*Design, manufacturing, final control* |
| **Stryker Spine**<br>*59 Route 17 South*<br>*Allendale, NJ 07401*<br>*United States* | **Conception, fabrication, contrôle final**<br>*Design, manufacturing, final control* |

## **Modifications** / *Modifications*

**Identification des modifications apportées au certificat CE n° 25231 rev. 12:**
*Identification of the modifications made to the CE certificate n° 25231 rev. 12:*

| **Modifications** / *Modifications* | **Dossier(s)** / *File(s)* **N°** | **Date** / *Date* |
|---|---|---|
| **Mise à jour de la liste des références** / *Update of list of references* | *T001271-P2-DOCA* | **26 mai 2021**<br>*May 26, 2021* |
| **Nouvelle référence de rapport dans le cadre du maintien de la certification** /<br>*New file reference in the framework of the maintenance of the certification* | *T001271-P1-R* | **4 août 2021**<br>*August 4, 2021* |

**GMED** **0459**

GMED - 38308 rev. 2
Modifie le document no. 38308 rev. 1

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

**On behalf of the President**
**Béatrice LYS**
**Technical Director**