

## ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

**GEXFIX SA**

**avenue de la Praille 50**

**1227 CAROUGE SWITZERLAND**

Catégorie du(des) dispositif(s) / Device(s) category

**Fiches invasives et fils de Kirschner stériles et non stériles  
pour fixateurs externes utilisés en traumatologie.**

*Sterile and non sterile invasive plugs and Kirschner wires  
used for external fixators used in trauma.*

Voir détails sur addendum / See attachment for additional information

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P147689-R, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

LNE/G-MED certifies that, on the basis of the results contained in the file referenced P147689-R, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : **September 9th, 2016 (included)**

Valable jusqu'au / Expiry date : **September 8th, 2019 (included)**



On behalf of the Certification Director

**Cécile VAUGELADE**

**G-MED Certification Division Manager**

### Identification des dispositifs / Identification of devices

Reference	Description	Class
1020-1025	Kirschner Wire 1.20 x 100 mm	IIb
1020-1026	Kirschner Wire 1.20 x 150 mm	IIb
1020-1027	Kirschner Wire Ti 1.20 x 150 mm	IIb
1020-1028	Kirschner Wire 1.80 x 250 mm tip threaded	IIb
1020-1029	Kirschner Wire 1.80 x 300 mm tip threaded	IIb
1020-1030	Kirschner Wire 1.80 x 400 mm	IIb
1020-1031	Kirschner Wire 1.80 x 150 mm	IIb
1020-1032	Kirschner Wire 2.50 x 300 mm	IIb
1020-1034	Kirschner Wire 2.50 x 250 mm tip threaded	IIb
1020-1035	Kirschner Wire 1.80 x 150 mm tip threaded	IIb
1020-1036	Kirschner Wire 3.00 x 300 mm	IIb
1020-1040	Kirschner Wire Ti 1.80 x 400 mm	IIb
1020-1041	Kirschner Wire Ti 1.80 x 150 mm	IIb
1020-1042	Kirschner Wire Ti 2.50 x 300 mm	IIb
1020-1043	Kirschner Wire Ti 2.50 x 250 tip threaded	IIb
1020-1044	Kirschner Wire Ti 1.80 x 150 tip threaded	IIb
1060-1001	Caslau - TGF wrist (sterile kit)	IIb
1060-1002	Digifix finger (sterile kit)	IIb
1060-1010	Adynex finger (sterile kit)	IIb
1060-1012	Gex-Finger finger (sterile kit)	IIb
2010-2010	Self drilling pin 1.5 x 50	IIb
2010-2016	Ti Self-drilling pin 1.5 x 50	IIb
2010-1020	Self drilling self tapping pin 3.00 x 70.00 x 20.00	IIb

**LNE/G-MED**

**0459**



**On behalf of the Certification Director**  
**Cécile VAUGELADE**  
**G-MED Certification Division Manager**

ADD

720 DM 0701-31 rev 5 du 28/07/2015

Reference	Description	Class
2010-1021	Ti Self-drilling pin 3 x 70	IIb
2015-1020	Self drilling self tapping pin 4.00 x 100.00 x 35.00	IIb
2015-1021	Ti Self-drilling pin 4 x 100	IIb
2015-1025	Self drilling self tapping pin 4.00 x 145.00 x 40.00	IIb
2015-1026	Ti Self-drilling pin 4 x 145	IIb
2015-1030	Self drilling self tapping pin 4.00 x 180.00 x 45.00	IIb
2015-1031	Ti Self-drilling pin 4 x 180	IIb
2020-1020	Self drilling self tapping pin 5.00 x 140.00 x 50.00	IIb
2020-1021	Ti Self-drilling pin 5 x 140	IIb
2020-1025	Self drilling self tapping pin 5.00 x 170.00 x 50.00	IIb
2020-1026	Ti Self-drilling pin 5 x 170	IIb
2020-1030	Self drilling self tapping pin 5.00 x 210.00 x 55.00	IIb
2020-1031	Ti Self-drilling pin 5 x 210	IIb
2020-1035	Self drilling self tapping pin 5.00 x 110.00 x 40.00	IIb
2020-1036	Ti Self-drilling pin 5 x 110	IIb
2030-1020	Transfixing pin 5.00 x 250.00 x 50.00	IIb
2030-1021	Ti Transfixing pin 5/4 x 250	IIb
2030-1025	Transfixing pin 5.00 x 200.00 x 50.00	IIb
2030-1026	Ti Transfixing pin 5/4 x 200	IIb

LNE/G-MED

0459



On behalf of the Certification Director  
**Cécile VAUGELADE**  
G-MED Certification Division Manager

ADD

720 DM 0701-31 rev 5 du 28/07/2015