

EC declaration of conformity according to the Annex VII of the European Directive 93/42/EEC related to the medical devices.

Manufacturer's name and address

The device is manufactured by the company:

Manufacturer Office
Pixee Medical 18 Rue Alain Savary 25000 BESANCON – France Phone: +33 (4) 58 10 13 65 Mobile: +33 (0)6 86 75 98 84 General Manager: M. Sébastien HENRY

Compliance Statement with relevant Directive

Pixee Medical ensures and declares, under its sole responsibility, that the Medical Device:

Reference	KNI001	KNI004	KNI005	KNI006	KNI007	KNI008	KNI009	KNI010	KNI011
Designation	Pointer	Ankle clamp	Bone reference	Orientation mechanism	Cutting guide adaptor	Universal cutting guide	Knee stylus	Control tool	Long Pointer
If applicable, software version	/								
Class	Class I according to the rule 1 and the rule 6 of the annex IX of the directive 93/42/EEC, amended by the directive 2007/47/EC.								

complies with the applicable provisions of the essential principles of the Directive 93/42/EEC.

This declaration is based on the documents of the Technical File HW001-KNEE_TOOLS-STED-002 ind.2 demonstrating compliance with the essential requirements of directive 93/42/EEC concerning medical devices.

Medical device nomenclature code


Product code according to different nomenclature systems of medical devices:

Nomenclature	Code and related description
CND	Z12130480 - Stereotactic orthopedic surgery instruments – hardware
GMDN	44054 Kit orthopedic surgery, general purpose, without any pharmaceutical substance, reusable
NBOG	MD 0106 Non-active instruments
UMDNS	13180: Prosthesis implantation instrument, orthopedic

Authorised signatory

The General Manager is the only one person authorised to sign this EC Declaration of Conformity.

Name	HENRY Sébastien
Position	CEO
Date	04/01/21

Signature, Company stamp
 <div style="display: inline-block; vertical-align: middle; text-align: left; margin-left: 20px;"> <p>SAS Pixee Medical 18, rue Alain Savary 25000 Besançon Siret 832 674 816 00034 APE 3250A N° TVA Intracommunautaire FR47832674816</p> </div>