Woven Orthopedic Technologies

Declaration of Conformity

Manufacturer

Woven Orthopedic Technologies
63 E. Center Street, Suite 3A
Manchester, CT
06040

Authorized Representative

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Products - Models / Classification / Rule:

OGmend® Implant Enhancement System (Annex II)				
REF	Description	Class	Rule	Start of CE Marking
11-6500M	OGmend® Implant; Medium Braided Sleeve	IIb	8	2018-10-05
11-8500L	OGmend® Implant; Large Braided Sleeve	IIb	8	2022-10-19
50-1003	Instrument, Inserter	IIa	6	2018-10-05

Woven Orthopedic Technologies declares that the above listed products comply with the essential requirements and provisions of Council Directive 93/42/EEC of June 14, 1993, including all amendments up to 2007/47/EC Annex II.3 for medical devices.

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC Annex II, excluding Section 4, for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Applicable Quality Standards: See Harmonized / Industry Standards (Tab 6)

ISO 13485 Certificate Number: FM 653914
EC Certificate Number: CE 654489

Notified Body:

BSI Group
Say Building, John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
CE 2797

Stephen Page (Management Representative)
Woven Orthopedic Technologies

October 19, 2022
Date