Paradigm Spine GmbH
Declaration of Conformity

Manufacturer / European Representative:

Paradigm Spine GmbH
Eisenbahnstrasse 84
78573 Wurmlingen
Germany

Product Name/Trade Name: coflex

General Product Description: Spinal Implant

Nomenclature Code and Description:

UMDNS code: 15-766
UMDNS term: Orthopädie-Fixationssystem, intern, spinal / Orthopedic Internal Fixation Systems, Spinal
EMDN code: P09070305
EMDN term: spinal stabilizers dynamic type
GMDN code: 35642
GMDN term: lumbar interspinous decompression spacer, sterile

Product List:

Part number	Description		Start of CE marking
	English	German	
UAI00008	coflex Interlaminar implant, 8mm	coflex Interlaminares Implantat, 8mm	05/2005
UAI00010	coflex Interlaminar implant, 10mm	coflex Interlaminares Implantat, 10mm	05/2005
UAI00012	coflex Interlaminar implant, 12mm	coflex Interlaminares Implantat, 12mm	05/2005
UAI00014	coflex Interlaminar implant, 14mm	coflex Interlaminares Implantat, 14mm	05/2005
UAI00016	coflex Interlaminar implant, 16mm	coflex Interlaminares Implantat, 16mm	05/2005
UBI00008	coflex Interlaminar implant, 8mm	coflex Interlaminares Implantat, 8mm	11/2008
UBI00010	coflex Interlaminar implant, 10mm	coflex Interlaminares Implantat, 10mm	11/2008
UBI00012	coflex Interlaminar implant, 12mm	coflex Interlaminares Implantat, 12mm	11/2008
UBI00014	coflex Interlaminar implant, 14mm	coflex Interlaminares Implantat, 14mm	11/2008
UBI00016	coflex Interlaminar implant, 16mm	coflex Interlaminares Implantat, 16mm	11/2008

Classification: class IIb according to 93/42/EEC Annex IX Rule 8

Conformity Assessment Route: 93/42/EEC Annex II without Section 4

We herewith declare that the DoC is issued under our sole responsibility and that the products listed above meet the relevant provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained at the premises of the manufacturer.

Standards Applied: Reference attached list of applied standards

Notified Body: TÜV SÜD Product Service GmbH (ID #0123)
Ridlerstrasse 65
80339 München
Germany

EC Certificate(s): G1 057034 0011 Rev. 01 (valid until May 26, 2024)

DIMDI Registration Number: DE/CA39/1197/01Ä2

Place, Date of Issue Wurmlingen, May 15, 2020

Signature [redacted]

List of Applied Standards

Standard	Title
ASTM F88/F88M-09	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F136-13	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
ASTM F1886 / F1886M-09	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F1929-98	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1980-07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F2052-02	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2119-07	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
ASTM F2182-11a	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
ASTM F2213-06	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
ASTM F2503-13	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
DIN 58953-6:2010	Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized
EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN 868-5:2009	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2-2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2006/AC:2009	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14602:2011	Non-active surgical implants - Implants for osteosynthesis - Particular requirements
EN ISO 14630:2009	Non-active surgical implants - General requirements
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 5832-3:1996	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

Paradigm Spine GmbH
Declaration of Conformity

Manufacturer / European Representative:

Paradigm Spine GmbH
Eisenbahnstrasse 84
78573 Wurmlingen
Germany

Product Name/Trade Name: coflex-F

General Product Description: Spinal Implant System

Nomenclature Code and Description:

UMDNS code: 15-766
UMDNS term: Orthopädie-Fixationssystem, intern, spinal / Orthopedic Internal Fixation Systems, Spinal
EMDN code: P09070302
EMDN term: Prosthesis, spinal fixation or stabilization systems – others
GMDN code: 61533
GMDN term: Interspinous spinal fixation implant

Product List:

Part number	Description		Start of CE marking
	English	German	
RCI00008	coflex-F system, 8mm	coflex-F System, 8mm	10/2007
RCI00010	coflex-F system, 10mm	coflex-F System, 10mm	10/2007
RCI00012	coflex-F system, 12mm	coflex-F System, 12mm	10/2007
RCI00014	coflex-F system, 14mm	coflex-F System, 14mm	10/2007
RCI00016	coflex-F system, 16mm	coflex-F System, 16mm	10/2007

Classification: class IIb according to 93/42/EEC Annex IX Rule 8

Conformity Assessment Route: 93/42/EEC Annex II without Section 4

We herewith declare that the DoC is issued under our sole responsibility and that the products listed above meet the relevant provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained at the premises of the manufacturer.

Standards Applied: Reference attached list of applied standards

Notified Body: TÜV SÜD Product Service GmbH (ID #0123)
Ridlerstrasse 65
80339 München
Germany

EC Certificate(s): G1 057034 0011 Rev. 01 (valid until May 26, 2024)

DIMDI Registration Number: DE/CA39/1197/10Ä3

Place, Date of Issue

Signature

[redacted]

Alberto Jurado, Management Representative

List of Applied Standards

Standard	Title
ASTM F88/F88M-09	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F136-13	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
ASTM F1886 / F1886M-09	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F1929-98	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1980-07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F2052-02	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2119-07	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
ASTM F2182-11a	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
ASTM F2213-06	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
ASTM F2503-13	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
DIN 58953-6:2010	Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized
EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN 868-5:2009	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 11137-1:2015	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2-2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2006/AC:2009	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14602:2011	Non-active surgical implants - Implants for osteosynthesis - Particular requirements
EN ISO 14630:2009	Non-active surgical implants - General requirements
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 5832-3:1996	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy