

Declaration of Conformity Form

Legal Manufacturer Name:
Teleflex Medical

Subcontractor Site Name:
See relevant manufacturing site below, this is also the subcontractor

Address:
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Address:
See relevant manufacturing site below, this is also the subcontractor

Notified Body: BSI

Notified Body Number: CE 2797

Product Name	Product Classification	Classification Rule	Conformity Pathway	CE Certificate Number	Design Certificate Number
EZ-IO® Tactical Power Driver	Class IIa	9	Annex V	CE540596	N/A
EZ-IO® Power Driver	Class IIa	9	Annex V	CE540596	N/A
EZ-IO® 15mm Needle Set	Class IIa	7	Annex V	CE540596	N/A
EZ-IO® 25mm Needle Set	Class IIa	7	Annex V	CE540596	N/A
EZ-IO® 45mm Needle Set	Class IIa	7	Annex V	CE540596	N/A
EZ-IO® Manual Needle Set	Class IIa	7	Annex V	CE540596	N/A
EZ-IO® 15mm Needle + Stabilizer Kit	Class IIa	7	Annex V	CE540596	N/A
EZ-IO® 25mm Needle + Stabilizer Kit	Class IIa	7	Annex V	CE540596	N/A
EZ-IO® 45mm Needle + Stabilizer Kit	Class IIa	7	Annex V	CE540596	N/A
EZ-Stabilizer™	Class Is	1	Annex V	CE540596	N/A
EZ-IO® TALON™ 38.5mm Manual Needle Set	Class IIa	7	Annex V	CE540596	N/A

Teleflex Medical declares that above documented product(s) meets the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC. The declaration authorizes Teleflex Medical to affix the CE-marking to the products listed herein.

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Template # ATH-FRM0079	Revision: 01	Issue Date: See Agile	Parent Document: ATH-WI0083
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Ida Foley

Tullamore, 06 July 2020

Print Name: Ida Foley
Title: Quality Systems Manager

Place and Date of Issue

Approvals

Function [Print Function Titles]	Approval	Date
Originator	Meabh Healy	As per COF2690
Quality Systems	Ida Foley	As per COF2690
Regulatory Affairs & Functional Manager	Gary Fahey	As per COF2690

Change History for Declaration of Conformity:

COF#	Revision	Date	Reason for Revision
1150	AA	20 th August 2015	Initial release of DC0041.
1224	AB	4 th September 2015	Add product code 9084-EU-001 for the EZ-IO [®] Starter Kit
1360	AC	29 th February 2016	Update to remove Vidacare LLC as subcontractor.
1942	AD	2 nd August 2017	Update to change the address of Coastal Life Technologies, Inc from 1803 Grandstand Dr., Suite 101, San Antonio, Texas 78238, USA to 7027 Fairgrounds Parkway, San Antonio, Texas 78238, USA
2143	AE	10 May 2018	Update to change the date CE Mark affixed for product code 9084-EU-001- EZ-IO [®] Starter Kit from 20 th August 2015 to the 4 th of September 2015. Update to Approvals.
2238	AF	24 July 2018	Addition of 9 product codes. Update Coastal Life address for code 9084-EU-001.
2603	AG	23 October 2019	Update to align with current DoC template.
2676	AH	12 th of May 2020	Corrected classification rules assigned to EZ-IO Power Drivers and EZ-IO Needle Sets as the previous DOC classification included rules that were related to products not included on this DOC. Added product code 9094 in support of finished good product release. Updated manufacturing site name from Lake Region Medical to Viant Upland, Inc to reflect company name change. Updated manufacturing site name from Coastal Life Technologies to Viant San Antonio, Inc to reflect company name change.

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2690	AJ	07 July 2020	Admin Change. Date of release for COF2676 updated to reflect the correct date of release.
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Change History for ATH-FRM0079:

Change Order Number	Revision	Date	Reason for Revision
0824	AC	23 rd April 2013	Update to provide more detail in Teleflex Medical Address as per regulatory requirements and introduction of change history table for FRM0079
1366	AD	12 th January 2016	Update to include notified body and notified body number, Change "Manufacturing Site Name" to "Subcontractor Site Name", Added "Manufacturing Site & Address" column to attachment 1.
DCO-035047	00	SEE AGILE	Upload to AGILE
DCO-036090	01	See Agile	Notified body number to be updated from CE0086 to CE2797. Header and footer to be updated to align with Global form.

Attachment 1 to Declaration of Conformity

Product Name	Product Code	Manufacturing Site & Address	Date CE Mark Affixed by Teleflex Medical
EZ-IO® Tactical Power Driver	9040	Sparton Onyx, LLC 2920 Kelly Ave, Watertown, South Dakota 57201, USA	20 th August 2015
EZ-IO® Power Driver	9058	Sparton Onyx, LLC 2920 Kelly Ave, Watertown, South Dakota 57201, USA	20 th August 2015
EZ-IO® Power Driver	9050	Arriol International Corporation Zona Franca San Isidro, Carreta San Isidro Km. 17, Santo Domingo, Dominican Republic	20 th August 2015
EZ-IO® 15mm Needle Set	9018-VC-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 15mm Needle Set	9018-EU-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 15mm Needle Set	9018-EE-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786,	20 th August 2015

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		USA	
EZ-IO® 15mm Needle Set	9018-ME-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 15mm Needle Set	9018-NO-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 15mm Needle Set	9018-VC-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 15mm Needle Set	9018-EU-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 15mm Needle Set	9018-EE-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 15mm Needle Set	9018-ME-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 15mm Needle Set	9018-NO-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 25mm Needle Set	9001-VC-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 25mm Needle Set	9001-EU-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 25mm Needle Set	9001-EE-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 25mm Needle Set	9001-ME-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 25mm Needle Set	9001-NO-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 25mm Needle Set	9001-VC-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015

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		USA	
EZ-IO® 25mm Needle Set	9001-EU-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 25mm Needle Set	9001-EE-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 25mm Needle Set	9001-ME-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 25mm Needle Set	9001-NO-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 45mm Needle Set	9079-VC-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 45mm Needle Set	9079-EU-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 45mm Needle Set	9079-EE-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 45mm Needle Set	9079-ME-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 45mm Needle Set	9079-NO-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 45mm Needle Set	9079-VC-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 45mm Needle Set	9079-EU-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 45mm Needle Set	9079-EE-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 45mm Needle Set	9079-ME-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015

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		USA	
EZ-IO® 45mm Needle Set	9079-NO-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® Manual Needle Set (25 mm)	9055	Arriol International Corporation Zona Franca San Isidro, Carreta San Isidro Km. 17, Santo Domingo, Dominican Republic	20 th August 2015
EZ-IO® Manual Needle Set (38.5 mm)	9094	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	12 TH May 2020
EZ-IO® 15mm Needle + Stabilizer Kit	9018P-VC-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 15mm Needle + Stabilizer Kit	9018P-EU-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 15mm Needle + Stabilizer Kit	9018P-EE-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	24 th July 2018
EZ-IO® 15mm Needle + Stabilizer Kit	9018P-ME-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	24 th July 2018
EZ-IO® 15mm Needle + Stabilizer Kit	9018P-NO-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	24 th July 2018
EZ-IO® 25mm Needle + Stabilizer Kit	9001P-VC-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 25mm Needle + Stabilizer Kit	9001P-EU-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO® 25mm Needle + Stabilizer Kit	9001P-EE-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	24 th July 2018
EZ-IO® 25mm Needle + Stabilizer Kit	9001P-ME-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	24 th July 2018
EZ-IO® 25mm Needle + Stabilizer Kit	9001P-NO-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	24 th July 2018

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Stabilizer Kit		2052 West 11 th Street, Upland, California 91786, USA	
EZ-IO [®] 45mm Needle + Stabilizer Kit	9079P-VC-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO [®] 45mm Needle + Stabilizer Kit	9079P-EU-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO [®] 45mm Needle + Stabilizer Kit	9079P-EE-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	24 th July 2018
EZ-IO [®] 45mm Needle + Stabilizer Kit	9079P-ME-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	24 th July 2018
EZ-IO [®] 45mm Needle + Stabilizer Kit	9079P-NO-005	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	24 th July 2018
EZ-Stabilizer™	9066-VC-005	Viant San Antonio, Inc. 7027 Fairgrounds Parkway, San Antonio, Texas 78238, USA	20 th August 2015
EZ-IO [®] T.A.L.O.N.™ Needle Set	9081-VC-006	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA	20 th August 2015
EZ-IO [®] Starter Kit	9084-EU-001	Viant Upland, Inc, 2052 West 11 th Street, Upland, California 91786, USA Sparton Onyx, LLC 2920 Kelly Ave, Watertown, South Dakota 57201, USA Coastal Life Technologies, Inc. 7027 Fairgrounds Parkway, San Antonio, Texas 78238, USA	04 September 2015

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