EU Declaration of Conformity

for the

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them, and the CE Mark may be affixed.

General Product Name:	Neoteryx Mitra® Microsampler Specimen Collection Device
Legal Manufacturer: (Name on Label)	Trajan Scientific Australia Pty Ltd 7 Argent Place, Ringwood VIC 3134 Australia
SRN:	AU-MF-000033924
Basic UDI-DI:	93387990MITRA3X
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Mitra® Microsampler Specimen Collection Device is a single-use, non-sterile device used as a specimen collector and for the storage and transport of blood and other biological fluids, for analytical and diagnostic analyses.
IVDR Classification:	**Class A;** [Classification Rule 5(c), Specimen Receptacle] **EDMN W0501010299 –** Capillary Blood Collection Devices – Other
Notified Body:	N/A
CE Certificate:	N/A Self-certified
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
IVDR Assessment Route:	Conformity Assessment as per Article 48 of EU-IVDR - Issuing of the Declaration of Conformity in accordance with Article 17 and Annex IV, after drawing up the technical documentation in Annexes II and III of the EU IVDR 2017/746.

Name: Anne Marie Whalen, PhD Position: Global Head, Regulatory Affairs

Signed: 
Electronically signed by: Anne Marie Whalen
Reason: Regulatory representative signs to confirm document complies with applicable regulatory requirements.
Date: Apr 13, 2023 11:49 EDT

Date and Place: Trajan Scientific Australia Pty Ltd
13 APRIL 2023

who is the natural and legal person with responsibility for the design, manufacture, packaging, and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
EU 2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements
ISO 10993-1:2021	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Appendix II – Product Listing/Schedule

Item Number*	Alternative Product Number**	Product Description	EMDN Code (applies to all products listed)
V10001	10001	10uL Mitra Clamshell (2-Sampler) 52/PK	EDMN W0501010299 – Capillary Blood Collection Devices - Other
V10003	10003	10uL Mitra Clamshell (4-Sampler) Eval 6/PK	
V10004	10004	10uL Mitra Clamshell (4-Sampler) 52/PK	
V100502	100502	10uL Mitra Cartridge (2-Sampler) Specimen Bag - Eval 8/PK	
V10101	10101	10uL Mitra Autorack (96-Sampler) EA	
V10103-A	10103-A	10uL Mitra Cartridge (2-Sampler) Specimen Bag 52/PK	
V10103-C	10103-C	10uL Mitra Cartridge (2-Sampler) Specimen Bag - Non-Serialized 52/PK	
V10109	10109	10uL Mitra Clamshell (2-Sampler) Specimen Bag 30/PK	
V10110	10110	10uL Mitra Clamshell (4-Sampler) Specimen Bag 30/PK	
V20000	20000	20uL Mitra Clamshell (1-Sampler) 52/PK	
V20001	20001	20uL Mitra Clamshell (2-Sampler) 52/PK	
V20003	20003	20uL Mitra Clamshell (4-Sampler) Eval 6/PK	
V20004	20004	20uL Mitra Clamshell (4-Sampler) 52/PK	
V200502	200502	20uL Mitra Cartridge (2-Sampler) Specimen Bag - Eval 8/PK	
V20101	20101	20uL Mitra Autorack (96-Sampler) EA	
V20103-A	20103-A	20uL Mitra Cartridge (2-Sampler) Specimen Bag 52/PK	
V20109	20109	20uL Mitra Clamshell (2-Sampler) Specimen Bag 30/PK	
V20110	20110	20uL Mitra Clamshell (4-Sampler) Specimen Bag 30/PK	
V30001	30001	30uL Mitra Clamshell (2-Sampler) 52/PK	

V30002	30002	30uL Mitra Clamshell (3-Sampler) 52/PK	
V30003	30003	30uL Mitra Clamshell (4-Sampler) Eval 6/PK	
V30004	30004	30uL Mitra Clamshell (4-Sampler) 52/PK	
V300502	300502	30uL Mitra Cartridge (2-Sampler) Specimen Bag - Eval 8/PK	
V30101	30101	30uL Mitra Autorack (96-Sampler) EA	
V30103-A	30103-A	30uL Mitra Cartridge (2-Sampler) Specimen Bag 52/PK	
V30109	30109	30uL Mitra Clamshell (2-Sampler) Specimen Bag 30/PK	
V30110	30110	30uL Mitra Clamshell (4-Sampler) Specimen Bag 30/PK	

*Item Number refers to Trajan Scientific Inventory Number
**Alternative Product Number refers to Customer-facing Ordering Number

DOC Version History

Version	Compiled by	Date	Description
00	Anne Marie Whalen	September 22, 2022	Initial DoC for Mitra family of Devices
01	Anne Marie Whalen	March 9, 2023	Addition of SRN (EUDAMED-assigned Single Registration Number)
02	Anne Marie Whalen	March 17, 2023	Correct Mitra DOC date(s) from 2022 to 2023
03	Anne Marie Whalen	March 30, 2023	Appendix II - Added reference to Alternative Product Number, the Customer-facing Ordering Number for Mitra Products. Added Explanation in footer for Product Table

Document Approval:

	Name	Position	Signature	Date
Prepared by	Imelda Gunawan	Senior Quality Business Partner	Imelda Gunawan Electronically signed by: Imelda Gunawan Reason: Author signs to confirm the accuracy of the document content. Date: Dec 21 2022 22:09 GMT+11	
Reviewed by	Anne Marie Whalen	Global Head of Regulatory Affairs	Electronically signed by: Anne Marie Whalen Reason: Regulatory representative signs to confirm document complies with applicable regulatory requirements. Date: Dec 21 2022 12:01 EST	
Approved by	Rick Barber	Chief Corporate Systems Officer	Electronically signed by: Rick Barber Reason: Quality representative signs to confirm document complies with Quality Management System. Date: Dec 21 2022 13:34 GMT+11	

Document Revision History

Revision	Modified by	Change Control No.	Description of Change
00	Anne Marie Whalen	QMS-CC145	New Form
01	Imelda Gunawan	QMS-CC145	Correcting the CC# and form title to match description in QP404.

Associated forms and procedures

Doc. No.	Document Title
QP404	Medical Device Compliance Folder

DOCUMENT END