Declaration of Conformity

for **OC-Auto Sampling Bottle 3**

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:	OC-Auto Sampling Bottle 3
Legal Manufacturer: (Name on Label)	**EIKEN CHEMICAL CO., LTD.** 4-19-9 Taito, Taito-ku, Tokyo 110-8408, Japan
SRN:	JP-MF-000018097
Basic UDI-DI:	4987026TD-OCSBZH
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	OC-Auto Sampling Bottle 3 is designed as a sampling device and a container for a faecal specimen. It is used together with the dedicated immunochemical analysers, OC-SENSOR series and their reagents intended for the measurement of human haemoglobin and calprotectin as *in vitro* diagnostics. The testing population includes asymptomatic participants in screening programs and patients with symptoms suspected of intestinal disorders. The sampling and test are noninvasive, using stool/faeces as test sample. Sampling with OC-Auto Sampling Bottle 3 is done manually, and the measurement is processed using the dedicated automated analysers by qualified personnel in clinical laboratories and hospitals.
IVDR Classification:	Class A [Rule 5]
Notified Body:	N/A
CE Certificate	N/A
EU Authorised Representative:	Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta
EU Authorised Representative SRN:	MT-AR-000000234
IVDR Assessment Route:	'For Class A: Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III of the EU IVDR 2017/746.'

Name Shinya Sadamoto **Position** Executive Officer, PRRC

Signed  **Date** 6/6/2022 **Place** Japan

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
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+AC:2018	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2019	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
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
EN 13612:2002+AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects

Appendix II – Product Listing/Schedule

Catalogue Number	Sub-Code	UDI-DI	Device Name	EMDN Code
V-PZ25	VCPZ25	04987026130088	OC-Auto Sampling Bottle 3	W05019001
	VCPZ27	04987026165400	OC-Auto Sampling Bottle 3 RED	
	VCPZ32	04987026205458	OC-Auto Sampling Bottle 3	
	VCPZ34	04987026208381	OC-Auto Sampling Bottle 3	
	VCPZ36	04987026232478	OC-Auto Sampling Bottle 3	
V-PZ26	VCPZ26	04987026130095	OC-Auto Sampling Bottle 3 without barcode	
	VCPZ30	04987026190976	OC-Auto Sampling Bottle 3 without barcode RED	
	VCPZ31	04987026190983	OC-Auto Sampling Bottle 3 without barcode BROWN	

Version History

Version	Compiled by	Date	Description
001	Takashi Enomoto, R. A. Department	22/04/2022	First Issue
002	Tadashi Yasuda, R.A. Department	11/05/2022	1) NB info deleted 2) Assessment Route revised 3) GMDN changed to EMDN 4) UDI-DI added
003	Tadashi Yasuda, R.A. Department	20/05/2022	Basic UDI-DI corrected
004	Tadashi Yasuda, R.A. Department	06/06/2022	Sub-Code/UDI-DI added