EU Declaration of Conformity *In Vitro* Diagnostic Medical Devices

Product Name	Product Code	EMDN Code
Amicon Ultra 4 mL	UFC8010xxD	W0580
Amicon Ultra 15 mL	UFC9010xxD	W0580

Basic UDI:	405484UFCCSC69
Risk Class:	Class A
Intended Use:	Amicon Ultra-4 and 15 centrifugal filter devices are disposable, single-use ultrafiltration filter devices for in vitro diagnostic use for processing biological solution in the 4-15 mL volume range. They are intended for concentrating biological samples e.g., serum, urine, cerebrospinal fluid and other body fluids prior to in vitro diagnostic analysis. Device intended to be single use and used by a laboratory professional.
Manufacturer (Name and Address)	Merck Millipore Ltd, Tullagreen, Carrigtwohill, Co. Cork, Ireland, T45 KD29
Manufacturer SRN	IE-MF-000003997
UK Responsible Person	Millipore (UK) Ltd. Kirkton Campus Fleming Road, Livingston, UK, EH54 7BN
Conformity Route	Annex II and Annex III Regulation (EU) 2017/746
Common Specifications (CS)	N/a
Notified Body	N/a
Quality Assurance System	ISO 9001:2015 Certified by DQS GmbH

Classification: The products listed in the enclosure are qualified as Devices in compliance with article 2, part 2 of Regulation (EU) 2017/746. The products listed in the enclosure are classified as being "*in-vitro* diagnostic medical devices" according to Article 47 of the Regulation (EU) 2017/746.

1, the undersigned, hereby declare that the in vitro diagnostic medical device(s) listed in the enclosure conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5th April 2017 on In Vitro Diagnostic Medical Devices.
All supporting documentation is retained on the premises of the manufacturer.

This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

Signed on behalf of Merck Millipore Ltd. by:

Signature: Elaine Kennedy *Electronically signed by: Elaine Kennedy Reason: Approved Date: Feb 2, 2023 23:11 GMT*

Email: elaine.kennedy@merckgroup.com

Elaine Kennedy
Head of Quality,
Merck Millipore Ltd.

Signature: Oleksandra Boreiko *Electronically signed by: Oleksandra Boreiko Reason: confirmed Date: Jan 31. 2023 17:40 GMT+1*

Email: oleksandra.boreiko@merckgroup.com

Oleksandra Boreiko, Dr.
Head of Devices and Equipment,
Merck KGaA, Frankfurter Str.

REVISION SHEET

Date	Version	Nature of Changes	Changed By
25/May/22	1.0	Initial Release	Suzanne Rice
29/Nov/22	2.0	Amended Basic UDI number Corrected Typo	Suzanne Melia