ZYMO RESEARCH

The Beauty of Science is to Make Things Simple

EU Declaration of Conformity 2017/746

Déclaration de Conformité UE 2017/746

CE IVD

Manufacturer

Fabricant

Zymo Research

ADDRESS 17062 Murphy Ave.

ADRESSE Irvine, CA 92614, USA

SRN **US-MF-000019308**

Authorised Representative

Mandataire

Biotika SAS

ADDRESS 42 route du Périmètre

ADRESSE 74940, Annecy, France

SRN **FR-AR-000045231**

Products

Produits

Basic UDI-DI	Product Description-*Descrition du produit*	Code
0850027600D4032B5	ZymoBIOMICS 96 MagBead DNA Kit (Lysis Rack)	D4302-E
0850027600D4032B5	ZymoBIOMICS 96 MagBead DNA Kit (No Lysis Matrix)	D4306-E
0850027600D4032B5	ZymoBIOMICS 96 MagBead DNA Kit (Lysis Tubes)	D4308-E
0850027600D5030B8	EZ DNA Methylation-Lightning Kit 50 Prep	D5030-E
0850027600D5030B8	EZ DNA Methylation-Lightning Kit 200 prep	D5031-E
0850027600D5030B8	EZ-96 DNA Methylation-Lightning MagPrep (4 x 96 Rxns)	D5046-E
0850027600D5030B8	EZ-96 DNA Methylation Lightning MagPrep (8 x 96 Rxns)	D5047-E
0850027600R1102F6	DNA/RNA Shield Collection Tube (100 pk)	N1082-E
0850027600R2140FM	Quick-RNA Viral Kit – DX (50 preps)	R1034-E
0850027600R2140FM	Quick-RNA Viral Kit - DX (200 preps)	R1035-E
0850027600R2140FM	Quick-RNA Viral 96 Kit - DX 2 x 96 Prep	R1040-E
0850027600R2140FM	Quick-RNA Viral 96 Kit - DX 4 x 96 Prep	R1041-E
08500276001112DY	DNA/RNA Shield (1x) - 1 Liter	R1100-1L-E
08500276001112DY	DNA/RNA Shield (1X) - 250 ml	R1100-250-E
08500276001112DY	DNA/RNA Shield (1X) - 50ml	R1100-50-E
0850027600R1101F4	DNA/RNA Shield-Fecal Collection Tube - DX	R1101-E

Basic UDI-DI	Product Description-*Descrition du produit*	Code
0850027600R1102F6	DNA/RNA Shield Collection Tube 10 Pack	R1102-10-E
0850027600R1102F6	DNA/RNA Shield Collection Tube 50 Pack	R1102-E
0850027600R1102F6	DNA/RNA Shield Lysis Tubes (Microbe) 50 pack	R1103-E
0850027600R1102F6	DNA/RNA Shield Lysis Tubes w/Swab (Microbe) - 50 pack	R1104-E
0850027600R1102F6	DNA/RNA Shield Lysis Tubes (Tissue) - 50 pack	R1105-E
08500276000709F2	DNA/RNA Shield Collection Tube w/ Swab (1mL fill)	R1107-E
08500276000709F2	DNA/RNA Shield Collection Tube w/ Swab (2mL fill)	R1109-E
0850027600R1160FL	DNA/RNA Shield SafeCollect Swab Collection Kit, 1ml	R1160-E
0850027600R1160FL	DNA/RNA Shield SafeCollect Swab Collection Kit, 2ml	R1161-E
08500276001112DY	DNA/RNA Shield (2X) - 125 ml	R1200-125-E
08500276001112DY	DNA/RNA Shield (2X) - 25 ml	R1200-25-E
08500276000709F2	DNA/RNA Shield Saliva Collection Kit - DX	R1210-E
0850027600R1160FL	DNA/RNA Shield SafeCollect Saliva Collection Kit	R1211-E
0850027600R2140FM	Quick-DNA/RNA Viral MagBead – 250 prep	R2140-E
0850027600R2140FM	Quick-DNA/RNA Viral MagBead - 1000 prep	R2141-E
0850027600R2140FM	Quick-DNA-RNA™ HT - Dx (250 preps)	R2150-E
0850027600R2140FM	Quick-DNA-RNA™ HT -Dx (1000 preps)	R2151-E
0850027600R1101F4	DNA/RNA Shield-Fecal Collection Tube - DX (1 tube/pk)	R1101-1-E
0850027600R1101F4	DNA/RNA Shield Fecal Collection Tube (with Beads) - DX (10 tubes/pk)	R1137-E
0850027600R1101F4	DNA/RNA Shield Fecal Collection Tube (with Beads) - DX (1 tube/pk)	R1137-1-E

This EU declaration of conformity is issued under the sole responsibility of Manufacturer.

Cette déclaration est établie sous la seule responsabilité du fabricant.

Classification Device in class A following rule 5 of Annex VIII of Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

Classification *Dispositif de classe A selon la règle 5 de l'Annexe VIII du Règlement 2017/746 du Parlement Européen et du Conseil sur les dispositifs médicaux de diagnostic in vitro du 5 avril 2017.*

We hereby declare that the above-mentioned products conform to the required technical documentation, in accordance with:

Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices: Annex II and Annex III

Nous déclarons par la présente que les produits susmentionnés sont conformes à la documentation technique requise, conformément à :

Règlement 2017/746 du Parlement Européen et du Conseil sur les dispositifs médicaux de diagnostic in vitro du 5 avril 2017 : Annexe II et Annexe III

We ensure and declare that the CE-IVD marked medical device, placed in the market meets the provisions of the Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices which apply to it.

Nous assurons et déclarons que le dispositif médical marqué mis sur le marché, satisfait aux exigences du Règlement 2017/746 du Parlement Européen et du Conseil sur les dispositifs médicaux de diagnostic in vitro du 5 avril 2017 qui s'appliquent à lui.

Annecy, December 06, 2024, *06 Décembre 2024*

Julie Ogi

Regulatory Officer