

EU DECLARATION OF CONFORMITY

The undersigned, on behalf of the company Panreac Química S.LU. located at Calle Garraf n ° 2 de Castellar del Vallès, registered in EUDAMED as a manufacturer of medical devices for in vitro diagnostics with the Single Registration Number (SRN) ES-MF-000029369

DECLARES THAT:

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer Panreac Química S.LU.

The In Vitro Diagnostic Medical Devices described in Table 1 annexed to this declaration including the univocal product reference with its UDI and basic UDI code in Table 2:

They comply with the general safety and performance requirements set out in ANNEX I of EU Regulation 2017/746 and therefore provide the assigned performance and the safety of persons is ensured provided that the products are used in accordance with their intended purpose.

All of them with the same product description as clinical diagnostic products and a class A risk classification according to Annex VIII of EU Regulation 2017/746.

Date and place

16/04/2024
Castellar del Vallès (Barcelona)

Name and function
Company representative



Sr. Joan Roget
General Manager

TABLE 1

Reference	Name	UDI
251002.1208	Immersion Oil (CE-IVD)	8432647000013
251085.1214	Ethanol 96% v/v (CE-IVD)	8432647000037
251085.1215	Ethanol 96% v/v (CE-IVD)	8432647000051
251086.1211	Ethanol absolute (CE-IVD)	8432647000075
251086.1212	Ethanol absolute (CE-IVD)	8432647000099
251086.1214	Ethanol absolute (CE-IVD)	8432647000112
251086.1215	Ethanol absolute (CE-IVD)	8432647000136
251086.9914	Ethanol absolute (CE-IVD)	8432647000150
251170.0914	Methylene Blue (CE-IVD)	8432647000174
251170.1608	Methylene Blue (CE-IVD)	8432647000198
251172.1209	Kühne's Methylene Blue Phenicated solution (CE-IVD)	8432647000211
251172.1211	Kühne's Methylene Blue Phenicated solution (CE-IVD)	8432647000235
251301.1211	Eosin Yellowish hydroalcoholic solution 1% (CE-IVD)	8432647000259
251338.1211	Giemsa's Azur-Eosin-Methylene Blue solution(slow)(CE-IVD)	8432647000273
251338.1212	Giemsa's Azur-Eosin-Methylene Blue solution(slow)(CE-IVD)	8432647000297
251338.1608	Giemsa's Azur-Eosin-Methylene Blue solution(slow)(CE-IVD)	8432647000310
251338.1610	Giemsa's Azur-Eosin-Methylene Blue solution(slow)(CE-IVD)	8432647000334
251338.1611	Giemsa's Azur-Eosin-Methylene Blue solution(slow)(CE-IVD)	8432647000358
251338.1612	Giemsa's Azur-Eosin-Methylene Blue solution(slow)(CE-IVD)	8432647000372
251567.1609	Folin-Ciocalteu's Reagent (CE-IVD)	8432647000396
251622.1607	Safranin O (CE-IVD) (C.I. 50240) for microscopy,	8432647000419
251769.2711	Xylene, mixture of isomers (CE-IVD)	8432647000433
251769.2714	Xylene, mixture of isomers (CE-IVD)	8432647000457
251774.1609	Lugol's Liquor with 0,4% of Iodine (diluted)(CE-IVD)	8432647000471
251774.1611	Lugol's Liquor with 0,4% of Iodine (diluted)(CE-IVD)	8432647000495
251803.1211	Alcohol-Acetone 7:3 (CE-IVD)	8432647000518
252531.1211	Gram-Hucker's Safranin O solution (CE-IVD)	8432647000532
252532.1211	Gram-Hucker's Crystal Violet Oxalate solution (CE-IVD)	8432647000556
252931.0715	Formaldehyde 3.7-4.0% w/v buffered to pH=7 and stabilized with methanol (CE-IVD)	8432647000570
252931.0716	Formaldehyde 3.7-4.0% w/v buffered to pH=7 and stabilized with methanol (CE-IVD)	8432647000594
252931.1211	Formaldehyde 3.7-4.0% w/v buffered to pH=7 and stabilized with methanol (CE-IVD)	8432647000617
252931.1214	Formaldehyde 3.7-4.0% w/v buffered to pH=7 and stabilized with methanol (CE-IVD)	8432647000631
252931.1215	Formaldehyde 3.7-4.0% w/v buffered to pH=7 and stabilized with methanol (CE-IVD)	8432647000655
252931.1315	Formaldehyde 3.7-4.0% w/v buffered to pH=7 and stabilized with methanol (CE-IVD)	8432647000679
252931.9914	Formaldehyde 3.7-4.0% w/v buffered to pH=7 and stabilized with methanol (CE-IVD)	8432647000693
253139.1214	Citrosol (Substitute of Xylene)(CE-IVD)	8432647000716
253139.1612	Citrosol (Substitute of Xylene)(CE-IVD)	8432647000730
253211.0914	Paraffin M.P. 56-58°C pellets (CE-IVD)	8432647000754
253594.1211	Papanicolaou's Solution EA 50 (CE-IVD)	8432647000778
253594.1212	Papanicolaou's Solution EA 50 (CE-IVD)	8432647000792
253594.1610	Papanicolaou's Solution EA 50 (CE-IVD)	8432647000815



253594.1611	Papanicolaou's Solution EA 50 (CE-IVD)	8432647000839
253892.1211	Papanicolaou's Solution OG 6 (CE-IVD)	8432647000853
253892.1212	Papanicolaou's Solution OG 6 (CE-IVD)	8432647000877
253892.1611	Papanicolaou's Solution OG 6 (CE-IVD)	8432647000891
253949.1211	Harris Hematoxylin solution (CE-IVD)	8432647000914
253949.1212	Harris Hematoxylin solution (CE-IVD)	8432647000938
253949.1610	Harris Hematoxylin solution (CE-IVD)	8432647000952
253998.1210	Blue for fast staining (Panoptic No. 3)(CE-IVD)	8432647000976
253998.1212	Blue for fast staining (Panoptic No. 3)(CE-IVD)	8432647000990
253999.1210	Eosin for fast staining (Panoptic No. 2)(CE-IVD)	8432647001010
253999.1212	Eosin for fast staining (Panoptic No. 2)(CE-IVD)	8432647001034
254101.1210	Fixing for fast staining (Panoptic No. 1)(CE-IVD)	8432647001058
254101.1212	Fixing for fast staining (Panoptic No. 1)(CE-IVD)	8432647001072
254766.1211	Mayer's Hematoxylin solution (CE-IVD)	8432647001096
254766.1610	Mayer's Hematoxylin solution (CE-IVD)	8432647001119
254807.0922	Kit for Fast Staining in Haematology (Fast Panoptic)(CE-IVD)	8432647001133
255069.2711	Isoparaffin H (Substitute of Xylene)(CE-IVD)	8432647001140
255069.2714	Isoparaffin H (Substitute of Xylene)(CE-IVD)	8432647001164
255115.0922	Reticulin Kit(CE-IVD)	8432647001188
255298.1212	Carazzi's Hematoxylin solution (CE-IVD)	8432647001263
255298.1610	Carazzi's Hematoxylin solution (CE-IVD)	8432647001287
256462.0905	Histofix ® Preservative ready to use (CE-IVD)	8432647001300
256462.0931	Histofix ® Preservative ready to use (CE-IVD)	8432647001324
256462.0943	Histofix ® Preservative ready to use (CE-IVD)	8432647001348
256462.0944	Histofix ® Preservative ready to use (CE-IVD)	8432647001362
256462.0955	Histofix ® Preservative ready to use (CE-IVD)	8432647001386
256462.0961	Histofix ® Preservative ready to use (CE-IVD)	8432647001409
256462.0962	Histofix ® Preservative ready to use (CE-IVD)	8432647001423
256462.0967	Histofix ® Preservative ready to use (CE-IVD)	8432647001447
256462.09118	Histofix ® Preservative ready to use (CE-IVD)	8432647001461
256462.09149	Histofix ® Preservative ready to use (CE-IVD)	8432647001485
256462.09150	Histofix ® Preservative ready to use (CE-IVD)	8432647001874
256649.0922	Gram-Hucker's Staining Kit (Droppers)(CE-IVD)	8432647001508
256876.3408	Paraffin Cleaner (CE-IVD)	8432647001553
256879.1210	Eosin Yellowish alcoholic solution 1% (CE-IVD)	8432647001577
256879.1212	Eosin Yellowish alcoholic solution 1% (CE-IVD)	8432647001591
256991.1212	Harris Hematoxylin modified solution (CE-IVD)	8432647001614
256991.1610	Harris Hematoxylin modified solution (CE-IVD)	8432647001638
256993.0415	Paraffin M.P. 55-58°C plasticized + DMSO pellets(CE-IVD)	8432647001652
256993.0933	Paraffin M.P. 55-58°C plasticized + DMSO pellets(CE-IVD)	8432647001676
257041.1608	Lugol's Liquor with 5% of Iodine (concentrated) (CE-IVD)	8432647001690
257041.1610	Lugol's Liquor with 5% of Iodine (concentrated) (CE-IVD)	8432647001713
257041.1611	Lugol's Liquor with 5% of Iodine (concentrated) (CE-IVD)	8432647001737
257462.0905	Histofix ® Preservative ready to use (pink)(CE-IVD)	8432647001751
257462.0961	Histofix ® Preservative ready to use (pink)(CE-IVD)	8432647001867



257462.0962	Histofix ® Preservative ready to use (pink)(CE-IVD)	8432647001775
258462.0955	Histofix ® - Safe Preservative ready to use (CE-IVD)	8432647001799
258462.0961	Histofix ® - Safe Preservative ready to use (CE-IVD)	8432647001812
258462.0962	Histofix ® - Safe Preservative ready to use (CE-IVD)	8432647001836

TABLE 2

Family	Name	Basic UDI
251002	Immersion Oil (CE-IVD)	84326472510023Y
251085	Ethanol 96% v/v (CE-IVD)	84326472510854W
251086	Ethanol absolute (CE-IVD)	84326472510864Y
251170	Methylene Blue (CE-IVD)	84326472511704N
251172	Kühne's Methylene Blue Phenicated solution (CE-IVD)	84326472511724S
251301	Eosin Yellowish hydroalcoholic solution 1% (CE-IVD)	84326472513014D
251338	Giemsa's Azur-Eosin-Methylene Blue solution(slow)(CE-IVD)	843264725133854
251567	Folin-Ciocalteu's Reagent (CE-IVD)	84326472515675M
251622	Safranin O (CE-IVD) (C.I. 50240) for microscopy,	843264725162254
251769	Xylene, mixture of isomers (CE-IVD)	843264725176963
251774	Lugol's Liquor with 0,4% of Iodine (diluted)(CE-IVD)	84326472517745U
251803	Alcohol-Acetone 7:3 (CE-IVD)	84326472518035A
252531	Gram-Hucker's Safranin O solution (CE-IVD)	843264725253157
252532	Gram-Hucker's Crystal Violet Oxalate solution (CE-IVD)	843264725253259
252931	Formaldehyde 3.7-4.0% w/v buffered to pH=7 and stabilized with methanol (CE-IVD)	84326472529315T
253139	Citrosol (Substitute of Xylene)(CE-IVD)	84326472531395A
253211	Paraffin M.P. 56-58°C pellets (CE-IVD)	84326472532114R
253594	Papanicolaou's Solution EA 50 (CE-IVD)	843264725359466
253892	Papanicolaou's Solution OG 6 (CE-IVD)	84326472538926H
253949	Harris Hematoxylin solution (CE-IVD)	84326472539496M
253998	Blue for fast staining (Panoptic No. 3)(CE-IVD)	843264725399872
253999	Eosin for fast staining (Panoptic No. 2)(CE-IVD)	843264725399974
254101	Fixing for fast staining (Panoptic No. 1)(CE-IVD)	84326472541014Q
254766	Mayer's Hematoxylin solution (CE-IVD)	84326472547666J
254807	Kit for Fast Staining in Haematology (Fast Panoptic)(CE-IVD)	843264725480767
255069	Isoparaffin H (Substitute of Xylene)(CE-IVD)	84326472550695U
255115	Reticulin Kit(CE-IVD)	84326472551155A
255298	Carazzi's Hematoxylin solution (CE-IVD)	84326472552986D
256462	Histofix ® Preservative ready to use (CE-IVD)	843264725646269
256649	Gram-Hucker's Staining Kit (Droppers)(CE-IVD)	84326472566496T
256876	Paraffin Cleaner (CE-IVD)	843264725687678
256879	Eosin Yellowish alcoholic solution 1% (CE-IVD)	84326472568797E
256991	Harris Hematoxylin modified solution (CE-IVD)	843264725699179
256993	Paraffin M.P. 55-58°C plasticized + DMSO pellets(CE-IVD)	84326472569937D
257041	Lugol's Liquor with 5% of Iodine (concentrated) (CE-IVD)	84326472570415L
257462	Histofix ® Preservative ready to use (pink)(CE-IVD)	84326472574626G
258462	Histofix ® - Safe Preservative ready to use (CE-IVD)	84326472584626P

