

EC Declaration of Conformity

Manufacturer name and address:

Plasti Lab S.A.R.L
Roumieh Industrial area
Main Road, El Khoury Bldg
P.O. Box 70407
Beirut, Lebanon

Authorized representative name and address:

CEpartner4U BV,
Esdoornlaan 13,
3951 DB Maarn,
The Netherlands

1. We declare that the product as listed below conforms to the requirements as per the In vitro diagnostic Medical Device Regulation (EU) 2017/746

Registration Number: NL-CA002-72816

Basic UDI-DI: 528116202SCQH

Product Group: Specimen Containers

Product Code: SCP-XXX, SSP-XXX, SCS-XXX – see Appendix

Intended purpose: Used for the collection, transportation and storage of a wide variety of specimens

2. The company undertakes to manufacture the products as per National/ International / Internal standards as specified in its Quality Systems and as per the requirements of IVDR 2017/746, ISO 9001:2015 & ISO 13485:2016, ISO 14971:2012 & ISO 15223-1:2021.
3. Company or its authorized representative shall fulfil the obligations imposed by the IVDR 2017/746 & ensures & declares that the Company's product shall meet all provisions of the directive as applicable.
4. Company undertakes to keep up-to-date a systematic procedure to review experience gained during post production phase and to implement appropriate means to apply any necessary corrective action taking account of the nature & risk in relation to the products.
5. Company undertakes to notify immediately any malfunction / deterioration of the performance of the device to the appropriate authority and recall such devices already placed in the market.

Dated: 20/04/2022

Joseph Khoury
General Manager
Plasti Lab S.A.R.L



2SC/DOC- I9

Appendix

Product Group 2: Specimen Container			Registration No.: NL-CA002-72816	
Product Code(s)	Product Description	State	Risk class / rule	First date of CE-compliance
SCS-3X0	Specimen Container, 30ml PS	Non-sterile	A	12/02/2015
SCS-3X0Y	Specimen Container, 30ml PS	Non-sterile	A	17/11/2020
SCS-6X0	Specimen Container, 60ml PS	Non-sterile	A	12/02/2015
SCS-6X0Y	Specimen Container, 60ml PS	Non-sterile	A	17/11/2020
SCP-6X0	Specimen Container, 60ml PP	Non-sterile	A	12/02/2015
SCP-6X0Y	Specimen Container, 60ml PP	Non-sterile	A	17/11/2020
SSP-6X0	Specimen Container, Stool 60ml PP	Non-sterile	A	12/02/2015
SSP-6X0Y	Specimen Container, Stool 60ml PP	Non-sterile	A	17/11/2020
SCP-1X0	Specimen Container, 120ml PP	Non-sterile	A	12/02/2015
SCP-1X0Y	Specimen Container, 120ml PP	Non-sterile	A	17/11/2020
SSP-1X0	Specimen Container, Stool 120ml PP	Non-sterile	A	12/02/2015
SSP-1X0Y	Specimen Container, Stool 120ml PP	Non-sterile	A	17/11/2020
SCP-5X0	Specimen Container, 150ml PP	Non-sterile	A	12/02/2015
SCP-5X0Y	Specimen Container, 150ml PP	Non-sterile	A	17/11/2020
SSP-5X0	Specimen Container, Stool 150ml PP	Non-sterile	A	12/02/2015
SSP-5X0Y	Specimen Container, Stool 150ml PP	Non-sterile	A	17/11/2020
SCP-325	24 Hour Urine Container, 2.5L, White	Non-Sterile	A	12/02/2015
SCP-325H	24 Hour Urine Container, 2.5L, White, with holder	Non-Sterile	A	17/11/2020
SCP-325A	24 Hour Urine Container, 2.5L, Amber	Non-Sterile	A	17/11/2020
SCP-325AH	24 Hour Urine Container, 2.5L, Amber, with Holder	Non-Sterile	A	17/11/2020
SCP-300	24 Hour Urine Container, 3L	Non-Sterile	A	12/02/2015

