

CDUE-115 Rev.0

Fecha/Date: 29/04/2022  
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El fabricante / *The manufacturer.*

**DELTALAB S.L.**

Plaza de la Verneda, 1 - Pol. Ind. La Llana  
08191 RUBI (BARCELONA) – ESPAÑA /SPAIN  
SRN: ES-MF-000000153

DECLARA BAJO SU EXCLUSIVA RESPONSABILIDAD /  
*DECLARES UNDER ITS SOLE RESPONSIBILITY*  
Que el producto / *that the product:*

|   |   |
|---|---|
| UDI-DI Básico / <i>Basic UDI-DI</i>                 | 84356058UDI-DI-156B   |
| Familia de producto /<br><i>Product family</i>      | RECIPIENTES PARA LA RECOGIDA DE MUESTRAS Y/O URINA<br>SAMPLES AND / OR URINE COLLECTION CONTAINERS<br>(Códigos según Anexo 1 / <i>Codes in Annex 1</i> )  |
| Finalidad Prevista /<br><i>Intended Use</i>         | Recogida de muestras biológicas y/o de orina, con el propósito de realizar un examen por diagnóstico in vitro.<br><i>Collection of biological and/or urine samples, for the purpose of in vitro diagnostic testing.</i> |
| Códigos GMDN y EMDN /<br><i>Codes GMDN and EMDN</i> | Código GMDN / <i>GMDN Code: Ver Anexo 1 / See Annex 1</i><br>Código EMDN / <i>EMDN Code: Ver Anexo 1 / See Annex 1</i>  |
| Clase del riesgo/<br><i>Risk Classification</i>     | Clase A, no estéril, (Regla 5c)<br><i>Class A, non-sterile (Rule 5c)</i>  |

CUMPLE CON / *CONFORMS WITH:*

**Reglamento (UE) 2017/746: Productos Sanitarios de Diagnóstico In Vitro**  
***Regulation (EU) 2017/746: In Vitro Diagnostic Medical Devices***

Consulte la lista de normas aplicables (armonizadas) en la documentación técnica /  
*Refer to the list of applicable (harmonized) standards in the Technical Documentation*

En/At Rubí (Barcelona) ESPAÑA/SPAIN

|  |   |
|--|---|
| José Saez<br>Director General / <i>Managing Director</i> | Anna Mir<br>Responsable Técnico / <i>Technical Director</i> |
|--|---|

  
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**ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS /**  
**ANNEX 1 – ARTICLES DESCRIPTION**

**Subfamilia de producto / Product subfamily:** RECIPIENTES PARA LA RECOGIDA DE MUESTRAS - NO ESTÉRILES / SAMPLE COLLECTION CONTAINERS - NON STERILE

**Código EMDN / EMDN Code:** W05030102

| REF.   | DESCRIPCIÓN / DESCRIPTION  | GMDN  |
|--------|--|-------|
| 202840 | FRASCO DE SEGURIDAD 20ML / SECURITY CONTAINER 20ML                     | 47775 |
| 202841 | FRASCO DE SEGURIDAD 40ML / SECURITY CONTAINER 40ML                     | 47775 |
| 202842 | FRASCO DE SEGURIDAD 60ML / SECURITY CONTAINER 60ML                     | 47775 |
| 202843 | FRASCO DE SEGURIDAD 90ML (Ø48-h75) / SECURITY CONTAINER 90ML (Ø48-h75) | 47775 |
| 202844 | FRASCO DE SEGURIDAD 120ML / SECURITY CONTAINER 120ML                   | 47775 |
| 202845 | FRASCO DE SEGURIDAD 250ML / SECURITY CONTAINER 250ML                   | 47775 |
| 202846 | FRASCO DE SEGURIDAD 500ML / SECURITY CONTAINER 500ML                   | 47775 |
| 202847 | FRASCO DE SEGURIDAD 1000ML / SECURITY CONTAINER 1000ML                 | 47775 |
| 202848 | FRASCO DE SEGURIDAD 90ML(Ø53-h68) / SECURITY CONTAINER 90ML(Ø53-h68)   | 47775 |
| 309201 | FRASCO 30ML PS ETIQUETADO / 30ML UNIVERSAL LABELLED PS                 | 47775 |
| 309202 | FRASCO 30ML PS / 30ML CONTAINER PS                                     | 47775 |
| 309222 | FRASCO 30ML PS B/U / 30ML CONTAINER I/W PS                             | 47775 |
| 309402 | FRASCO 40ML PS / PS 40ML CONTAINER                                     | 47775 |
| 309501 | FRASCO 60ML PS ETIQUETADO / PS 60 ML CONTAINER PRINTED LBL             | 47775 |
| 309502 | FRASCO 60ML PS / 60ML CONTAINER PS                                     | 47775 |
| 309505 | FRASCO 60ML PS T/AZUL / CONTAINER PS 60ML BLUE CAP                     | 47775 |
| 309552 | FRASCO 60ML PS C/ESPATULA / 60ML CONTAINER PS WITH SPOON               | 47775 |
| 309602 | FRASCO 30ML PS CON ESPATULA / 30ML CONTAINER WITH SPOON PS             | 47775 |
| 409201 | FRASCO 30ML PP ETIQUETADO / 30ML CONTAINER LABEL PP                    | 47775 |
| 409202 | FRASCO 30ML PP / 30ML CONTAINER PP                                     | 47775 |
| 409222 | FRASCO 30ML PP BOLSA UNITARIA / 30ML CONTAINER I/W PP                  | 47775 |
| 409402 | FRASCO 40ML PP GRADUADO / 40ML CONTAINER PP GRADUATED                  | 47775 |
| 409426 | FRASCO 40ML PP B/U GRADUADO / 40ML CONTAINER I/W PP                    | 47775 |

| REF.      | DESCRIPCIÓN / DESCRIPTION   | GMDN  |
|-----------|---|-------|
| 409501    | FRASCO 60ML PP ETIQUETADO / 60ML CONTAINER LABELLED PP                  | 47775 |
| 409502    | FRASCO 60ML PP / 60ML CONTAINER PP                                      | 47775 |
| 409511    | FRASCO 60ML PP ETIQUETADO T/AZUL / 60ML BLUE CONTAINER LABEL PP         | 47775 |
| 409552    | FRASCO 60ML PP C/ESPATULA / 60ML CONTAINER W/SPOON                      | 47775 |
| 409557    | FRASCO 60ML PP C/ESPATULA T/VERDE / CONTAINER 60ML PP W/SPOON GREEN CAP | 47775 |
| 409602    | FRASCO 30ML PP C/CUCHARA / 30ML CONTAINER WITH SPOON PP                 | 47775 |
| 409701    | FRASCO 150ML PP ETIQUETADO / 150ML CONTAINER LABELLED PP                | 47775 |
| 409703    | FRASCO 150ML PP SIN ROSCAR / 150ML CONT SEPARATED CAP PP                | 47775 |
| 409707    | FRASCO 150ML PP T/VERDE / PP 150 ML CONTAINER GREEN CAP                 | 47775 |
| 409711    | FRASCO 150ML AZUL ETIQUETADO / 150ML BLUE CONTAINER LABEL PP            | 47775 |
| 409752    | FRASCO 150ML PP C/CUCHARA / 150ML CONTAINER WITH SPOON PP               | 47775 |
| 409756    | FRASCO 150ML PP ESPATULA B/U / 150ML CONTAINER PP SPOON I/W             | 47775 |
| 409802    | FRASCO 50ML PP / 50ML CONTAINER PP                                      | 47775 |
| 409826    | FRASCO 50ML PP B/U / 50ML CONTAINER I/W PP                              | 47775 |
| 409852    | FRASCO 50ML PP CON ESPATULA / 50ML CONTAINER WITH SPOON PP              | 47775 |
| 409902    | FRASCO 200ML PP / CONTAINER 200ML PP                                    | 47775 |
| 409905    | FRASCO 200ML PP AZUL TRANS.ETI / CONTAINER 200 ML PP BLUE-PLAIN LBL     | 47775 |
| 410047    | FRASCO 50ML PP T/SIN PRECINTO / CONTAINER 50ML PP NO TAMPER EVIDENT CAP | 47775 |
| 419802    | FRASCO 50ML PP T/PRECINTO / 50ML CONT SEALED CAP PP                     | 47775 |
| 419826    | FRASCO 50ML PP T/PRECINTO B/U / 50ML CONT SEALED CAP I/W PP             | 47775 |
| 202844/T  | FRASCO DE SEGURIDAD 120ML TAPADO / SECURITY CONTAINER 120ML CAPPED      | 47775 |
| 202847/T  | FRASCO DE SEGURIDAD 1000ML TAPADO / SECURITY CONTAINER 1000ML CAPPED    | 47775 |
| 309202.NR | FRASCO 30ML PS / 30ML CONTAINER PS NO SCREW                             | 47775 |
| 309202.WO | FRASCO 30ML PS SIN TAPÓN / CONT.30ML PS NO CAP                          | 47775 |
| 309202V   | FRASCO 30ML PS TAPÓN VERDE / 30ML CONTAINER PS GREEN CAP                | 47775 |

| REF.      | DESCRIPCIÓN / DESCRIPTION   | GMDN  |
|-----------|---|-------|
| 309222.1  | FRASCO 30ML PS B/U ETIQUETADO / CONTAINER 30 ML. UNIT BAG LABEL             | 47775 |
| 309501BE  | FRASCO 60ML PS B/50 CÓD.BARRAS / 60ML PS CONTAINER B/50 BAR COD             | 47775 |
| 309502.10 | FP-60 S/ROSCAR C/600 T/ROJO / CONT.60ML C/600 RED CAP                       | 47775 |
| 309502.6  | FRASCO 60 ML.PS ETIQUETA BLANC / PS 60 ML. CONTAINER PLAIN LABEL            | 47775 |
| 409202.WO | FRASCO 30ML PP SIN TAPÓN / CONT. 30ML PP NO CAP                             | 47775 |
| 409203.2  | FRASCO 30ML PP T/BLAN ENV. SEP / PP 30 ML+ WHITE CAP SEPARAT.C/1800         | 47775 |
| 409203.2A | FR.30ML PP T/BL.ENV.SEP.C/ANON / PP 30ML WHITE CAP SEP.PLAIN BO             | 47775 |
| 409502.4  | FRASCO 60ML S/ROSCAR 38X65 PP / 60ML CONT. UNCAPPED 38X65MM PP              | 47775 |
| 409502G   | FRASCO 60ML PP GRADUADO / 60ML CONTAINER GRADUATED PP                       | 47775 |
| 409502G.4 | FR.60 GRAD.S/ROSCAR TAP.SEPARA / CONT.60 GRAD.UNCAPPED SEP.CAP              | 47775 |
| 409502G.Y | FRASCO 60ML PP GRADUADO T/AMARILLO / CONTAINER 60ML PP YELLOW CAP SCREWED   | 47775 |
| 409507G   | FRASCO 60ml PP GRAD.T/VERDE / 60ml CONT.PP GRAD.GREEN CAP                   | 47775 |
| 409511.4  | FR.60ML AZUL CLARO S/ETIQUETA / 60ML LIGHT BLUE CONTAINER                   | 47775 |
| 409511.5  | FR.60ML AZUL TRANSL.ETIQ. BLANC / 60ML CONTAINER TRANS.BLUE LBL             | 47775 |
| 409511.5A | FR.60ML AZUL TRANSL.ETIQ. BLANC / 60ML CONTAINER TRANS.BLUE LBL             | 47775 |
| 409512    | FRASCO 60ML PP T/ROJO C/CUCHARA C/GRIS / 60ML CONTAINER TRANS.BLUE LBL      | 47775 |
| 409602E   | FRASCO 30 ML.PP. CUCHARA ETIQ. / 30ML CONTAINER W/SPOON PP LABE             | 47775 |
| 409702    | FRASCO 150ML PP / 150ML CONTAINER PP  | 47775 |
| 409702B   | FRASCO 150ML PP B/50 / 150ML CONTAINER PP B/50                              | 47775 |
| 409702.P  | FRASCO 150ML PP ROSCADO / 150ML PP CUPPED CONTAINER                         | 47775 |
| 409756.50 | FRASCO 150ML PP ESPATULA B/U BOLSA 50 / CONTAINER 150ML PP I/W SPOON BAG/50 | 47775 |
| 409805.6  | FRASCO 50ML PP T/ROJO SEPARADO / 50ML PP CONTAINER SEP.RED CAP              | 47775 |
| 409902.4  | FRASCO 200ML PP S/ROSCAR / 200ML CONTAINER PP SEPAR.CAP                     | 47775 |
| 409902P   | FRASCO 200ML PP / CONTAINER 200ML PP  | 47775 |
| 175723    | TUBO 5ML PS 13X75 PS TAPADO ROJO / 5ML TUBE PS 13X75 CAPPED RED             | 47775 |

| REF.   | DESCRIPCIÓN / DESCRIPTION  | GMDN  |
|--------|--|-------|
| 175724 | TUBO 10ML PS 16X95 TAPADO ROJO / 10ML TUBE PS 16X95 CAPPED RED           | 47775 |
| 300300 | TUBO 4 ML PS 11X70 MM / TUBE 11X70 PS                                    | 47775 |
| 300400 | TUBO 6 ML PS 12X88 MM GRADUADO / TUBE 12X88 PS GRADUATED                 | 47775 |
| 300500 | TUBO 11X55MM PS 3 ML / TUBE 11X55MM PS 3ML                               | 47775 |
| 300700 | TUBO 13X75 PS / TUBE 13X75 PS  | 47775 |
| 300702 | TUBO 13X75 PS TAPADO / TUBE 13X75 PS CAPPED                              | 47775 |
| 300704 | TUBO 13X75 PS TAPADO Y ETIQ / TUBE 13X75 PS CAPPED&LABELLED              | 47775 |
| 300705 | TUBO 10 ML PS 16X100 MM / TUBE 16X100 PS                                 | 47775 |
| 300800 | TUBO 5 ML PS 12X75 MM GRADUADO / TUBE 5ML PS 12X75MM GRADUATED           | 47775 |
| 300802 | TUBO 12X75 PS + TAPON 305802 / PS TUBE 12X75 + CAP 305802                | 47775 |
| 300900 | TUBO 10 ML PS 16X95 MM GRADUADO / TUBE 10ML PS 16X95MM GRADUATED         | 47775 |
| 300903 | TUBO 16x95 PS TAPADO / TUBE 16x95 POLYSTYRENE CAPPED                     | 47775 |
| 300904 | TUBO 10 ML PS 16X95 MM TAPADO ETIQUETADO / TUBE 16X95 PS CAPPED LABELLED | 47775 |
| 300907 | TUBO 16X100 PS TAPADO / TUBE 16X100 PS CAPPED                            | 47775 |
| 300908 | TUBO 16X100 PS TAPADO Y ETIQ / TUBE 16X100 PS CAPPED LABELLED            | 47775 |
| 300913 | TUBO 15X95 PS TAPADO / TUBE 16X95 PS CAPPED                              | 47775 |
| 301200 | TUBO CONICO 16X102 PS / CONICAL TUBE 16X102 PS                           | 47775 |
| 301201 | TUBO CONICO 12ML PS 16X100 MM / CONICAL TUBE 16X100 PS                   | 47775 |
| 301202 | TUBO CONICO 16X102 PS / CONICAL TUBE 16X102 PS                           | 47775 |
| 301205 | TUBO CONICO 301200 TAP/305502 / PS TUBE 12ML CONICAL CAPPED              | 47775 |
| 301403 | TUBO 12ML PS 15X102 MM TAPADO FALDON / TUBE 12ML PS CAPPED               | 47775 |
| 301700 | TUBO 7 ML PS 13X100 MM / TUBE 13X100 PS                                  | 47775 |
| 304208 | TUBO 5ML C/FALDON T/MALVA / TUBE 5ML SKIRTED MAUVE CAP                   | 47775 |
| 400400 | TUBO 6 ML PP 12X88 MM GRADUADO / TUBE 12X88 PP GRADUATED                 | 47775 |
| 400500 | TUBO 3 ML PP 11X55 MM / TUBE 11X55 PP                                    | 47775 |
| 400700 | TUBO 5 ML 13X75 MM / TUBE 13X75 PP                                       | 47775 |
| 400705 | TUBO 10 ML PP 16X100 MM / TUBE 16X100 PP                                 | 47775 |
| 400800 | TUBO 5 ML PP 12X75 MM GRADUADO / TUBE 5ML PP 12X75MM GRADUATED           | 47775 |



| REF.      | DESCRIPCIÓN / DESCRIPTION  | GMDN  |
|-----------|--|-------|
| 400900    | TUBO 16X95 PP / TUBE 16X95 PP  | 47775 |
| 400903    | TUBO 10ML PP 16X95 TAPADO ROJO / 10ML TUBE PP 16X95 CAPPED RED                     | 47775 |
| 400908    | TUBO 16x95 TAPADO 305007 / 16X95 PP TUBE CAPPED 305007                             | 47775 |
| 401100    | TUBO 5 ML PP 15X50 MM / TUBE 15X50 PP  | 47775 |
| 401200    | TUBO CONICO 12 ML PP 16X102 MM / CONICAL TUBE 16X102 PP                            | 47775 |
| 401201    | TUBO CONICO 12 ML PP 16x100 MM / CONICAL TUBE 16X100 PP                            | 47775 |
| 401204    | TUBO CONICO 12 ML PP 16X100 MM / CONICAL TUBE 12ML PP 16X100MM                     | 47775 |
| 401300    | TUBO CONICO 16X102 PP TAPADO / CONICAL TUBE 16x102 PP CAPPED                       | 47775 |
| 401403    | TUBO 12ML PP 15X102 MM TAPADO FALDON / PP 12 ML TUBE CAPPED                        | 47775 |
| 401700    | TUBO 7 ML PP 13X100 MM / PP TUBE 13X100  | 47775 |
| 300500MI  | TUBO 11X55 PS / TUBE 11X55 PS  | 47775 |
| 300800.1  | TUBO 5 ML PS 12X75 MM SIN ENRASES / TUBE 12X75 PS                                  | 47775 |
| 300800.2  | TUBO 12X75 PS REFORZADO / TUBE 12X75 PS  | 47775 |
| 300900M   | TUBO 16X95 PS GRAD.CAJA 5X100 / TUBE 16X95 PS GRAD.CASE 5X100                      | 47775 |
| 400500.B  | TUBO 11x55 PP B/400 / TUBE 11x55 PP B/400  | 47775 |
| 400800.1  | TUBO 5 ML PP 12X75 MM SIN ENRASES / TUBE 12X75 WITHOUT RINGS PP                    | 47775 |
| 420900E   | TUBO 12ML PP S/TAPON C/FALDON / PP 12ML TUBE W/SKIRT W/OUT CAP                     | 47775 |
| 429900SP  | TUBO 50ML PP CONICO SIN ROSCAR / 50ML CONICAL TUBE PP SEP.CAP                      | 47775 |
| 429901SP  | TUBO CONICO 50ML PP FALDON SIN ROSCAR / TUBE 50ML PP SKIRTED SEP. CAP              | 47775 |
| 429910SP  | TUBO 15ml PP CONICO SIN ROSCAR / 15ml CONICAL TUBE PP SEP.CAP                      | 47775 |
| 429927S/E | TUBO CONICO 50ML C/FALDON B/U / 50ML CONICAL TUBE SKIRT I/W PP                     | 47775 |
| 300800.1B | TUBO 5 ML PS 12X75 MM SIN ENRASES / TUBE 5ML PS 12X75 MM NO FLUSH R/BOX            | 47775 |
| 401403B   | TUBO 12ML PP 15X102 MM TAPADO FALDON / TUBE 12ML PP 15X102 MM CAPPED SKIRTED R/BOX | 47775 |
| 300700B   | TUBO 13X75 PS / TUBE 13X75 PS R/BOX  | 47775 |
| 400700B   | TUBO 5 ML PP 13X75 MM / TUBE 5ML PP 13X75 MM R/BOX.                                | 47775 |
| 429900    | TUBO CONICO 50ML PP TAPADO / 50ML CONICAL TUBE PP                                  | 47775 |
| 429901    | TUBO 50ML PP CONICO FALDON / 50ML CONICAL TUBE SKIRT PP                            | 47775 |
| 429903    | TUBO 50ML PP CON.FALDON S/TAP / 50ML CON.TUBE SKIRTE PP NO CAP                     | 47775 |

| REF.     | DESCRIPCIÓN / DESCRIPTION   | GMDN  |
|----------|---|-------|
| 429910   | TUBO CONICO 15ML PP TAPADO / 15ML CONICAL TUBE PP                               | 47775 |
| 429930   | TUBO 50ML PP CONICO IMPRESO B/25 / 50ML TUBE PP CONICAL PRINT 25/B              | 47775 |
| 429940   | TUBO 15 ML PP CONICO IMPRESO GRANEL / 15ML TUBE PP CONICAL PRINTED IN BULK      | 47775 |
| 429945   | TUBO 15 ML PP CONICO IMPRESO B/25 / 15ML TUBE PP CONICAL PRINT 25/B             | 47775 |
| 429950   | TUBO 50 ML PP CONICO IMPRESO C/F B/25 / 50ML TUBE PP CONICAL PRINT SKIRTED 25/B | 47775 |
| 409502BO | FRASCO 60ML PP C/A.BORICO / 60ML CONTAINER PP W/BORIC A.                        | 63348 |
| 400706E  | TUBO 10ML C/A.BORICO TAP.ETIQ. B/U / 100ML TUBE W/BORIC A. CAP.LAB. I/W         | 63348 |

**Subfamilia de producto / Product subfamily:** RECIPIENTES PARA LA RECOGIDA DE ORINA - NO ESTÉRILES / URINE COLLECTION CONTAINERS - NON STERILE

**Código EMDN / EMDN Code:** W05010203

**Código GMDN / GMDN Code:** 57919

| REF.      | DESCRIPCIÓN / DESCRIPTION  |
|-----------|--|
| 407001    | FRASCO 2L NATURAL / CONTAINER 2L NATURAL                           |
| 407003    | FRASCO 2L MARRON / CONTAINER 2L BROWN                              |
| 407005    | FRASCO 2,7L 24H NATURAL / CONTAINER 2.7L 24H NATURAL               |
| 407006    | FRASCO 2,7L 24H MARRON / CONTAINER 2.7L 24H BROWN                  |
| 407008    | FRASCO 2L NATURAL B/U / CONTAINER 2L I/W NATURAL                   |
| 408001    | FRASCO CILÍNDRICO 2L NATURAL / CYLINDRICAL CONT 2L NATURAL         |
| 408610    | FRASCO 3L MARRON TAPON BLANCO / CONTAINER 3L BROWN WHITE CAP       |
| 407001/T  | FRASCO 2L NATURAL TAPADO / CONTAINER 2L NATURAL CAPPED             |
| 407001OBT | FRASCO 2L NATURAL C/OBTURADOR / CONTAINER 2L NATURAL W/PLUG        |
| 407005/T  | FRASCO 2,7L 24 H NATURAL C/TAPA / CONTAINER 2.7L 24H NATURAL W/LID |
| 407006/T  | FRASCO 2,7L 24H MARRON C/TAPA / CONTAINER 2.7L 24H BROWN W/LID     |
| 407008OBT | FRASCO 2L T/NEGRO OBT B/U / CONT 2L BLACK CAP + PLUG I/W           |
| 408001.1  | FRASCO 2L CILINDRICO B/U / CYLINDRICAL CONT 2L I/W                 |
| 408001-86 | FRASCO 2L CILINDRICO Ø 86 MM / CYLINDRICAL CONT PUSH CAP 2L        |
| 408001O/T | FRASCO 2L CIL T/NEG OBT TAPADO / CYLINDRICAL CONT 2L B/CAP W/PL    |
| 408001OBT | FRASCO 2L CILINDRICO OBTURADOR / CYLINDRICAL CONT 2L W/PLUG        |
| 408001OTA | FRASCO 2L NATURAL OBT T/NEGRO / 24H CYL.CONT. BLACK CAP            |