

|                                |                                        |
|--------------------------------|----------------------------------------|
| <b>Article code</b>            | 7751916                                |
| <b>Article name acc. DoC</b>   | Amika EasyBag mobile with cover, ENFit |
| <b>Class acc. MDR 2017/745</b> | Ila                                    |

| Article code | Article name                   | Material                                                                                                                                                                                   |
|--------------|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| C10419       | Amika clamp                    | <ul style="list-style-type: none"> <li>●PC (Polycarbonate) based on Bisphenole A</li> <li>●Colorbatch lilac</li> </ul>                                                                     |
| C11503       | Solvent                        | ●THF (Tetrahydrofuran), also 1,4-Epoxy butane                                                                                                                                              |
| C11553       | Solvent                        | ●CHN (Cyclohexanone)                                                                                                                                                                       |
| C30844       | ENFit male cap, vented         | ●PP (Polypropylene)                                                                                                                                                                        |
| C30931       | Tube 3 x 5 mm                  | ●PVC (Polyvinylchloride) noDOP with plasticizer TEHTM (Tri-(2-ethylhexyl) trimellitate)                                                                                                    |
| C60931       | Tube 3 x 5 mm                  | ●PVC (Polyvinylchloride), plasticizer TOTM, stabiliser calcium / zinc, natural - unpigmented                                                                                               |
| J1040202     |                                |                                                                                                                                                                                            |
| C30293       | ENFit stopcock handle          | ●HDPE (high density polyethylene) with colourant                                                                                                                                           |
| C30294       | ENFit stopcock housing         | ●Copolyester (BPA-free)                                                                                                                                                                    |
| C30295       | Silicone oil SILFAR 350        | ●PDMS (Polydimethylsiloxane)                                                                                                                                                               |
| C30297       | ENFit stopcock handle FK       | <ul style="list-style-type: none"> <li>●HDPE (high density polyethylene)</li> <li>●colourbatch purple</li> </ul>                                                                           |
| C30298       | ENFit stopcock housing FK      | ●Copolyester (BPA-free)                                                                                                                                                                    |
| C30823       | ENFit female cap               | <ul style="list-style-type: none"> <li>●HDPE (high density Polyethylene)</li> <li>●colourant violet</li> </ul>                                                                             |
| C30878       | ENFit Stopcock 5.0 mm (open)   | <ul style="list-style-type: none"> <li>●housing: Copolyester (BPA-free)</li> <li>●handle: HDPE (high density polyethylene) with colourant</li> <li>●PDMS (Polydimethylsiloxane)</li> </ul> |
| C30897       | Strap for ENFit male connector | ●LDPE (Low density polyethylene)                                                                                                                                                           |
| J1040220S    |                                |                                                                                                                                                                                            |
| C11499       | Petroleum ether                | ●N/A                                                                                                                                                                                       |
| C11503       | Solvent                        | ●THF (Tetrahydrofuran), also 1,4-Epoxy butane                                                                                                                                              |
| C11511       | Lubricant                      | ●Aminofunctional Siloxane                                                                                                                                                                  |
| C30776       | ENFit female 5.0 mm            | <ul style="list-style-type: none"> <li>●Copolyester (BPA-free)</li> <li>●RAL 4005 (violet), Colour concentrate</li> </ul>                                                                  |
| C30953       | Tube 3.5 x 5.0 mm              | ●PVC (Polyvinylchloride) with plasticizer TOTM                                                                                                                                             |
| J1040254     |                                |                                                                                                                                                                                            |
| C10594       | Protective cap for ENPlus      | ●PP (Polypropylene)                                                                                                                                                                        |
| C10897       | Sealing for Cross spike        | ●LDPE (low density polyethylene) + EPE (foamed PE)                                                                                                                                         |
| C11503       | Solvent                        | ●THF (Tetrahydrofuran), also 1,4-Epoxy butane                                                                                                                                              |
| C30106       | Retainer nut ENPlus            | <ul style="list-style-type: none"> <li>●PP (Polypropylene)</li> <li>●Colourant lilac</li> </ul>                                                                                            |

| Article code  | Article name                          | Material                                                                                                          |
|---------------|---------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| C30602        | Adaptor EasyBag spike                 | ●PUR (Polyurethane)                                                                                               |
| C30820        | ENPlus spike                          | ●ABS (Acrylonitrile Butadiene Styrene)<br>●Carrier: Novodur P2H-AT<br>●Components: Inorganic and organic pigments |
| J1040289      |                                       |                                                                                                                   |
| C10594        | Protective cap for ENPlus             | ●PP (Polypropylene)                                                                                               |
| C10897        | Sealing for Cross spike               | ●LDPE (low density polyethylene) + EPE (foamed PE)                                                                |
| C11503        | Solvent                               | ●THF (Tetrahydrofuran), also 1,4-Epoxy butane                                                                     |
| C30106        | Retainer nut ENPlus                   | ●PP (Polypropylene)<br>●Colourant lilac                                                                           |
| C30602        | Adaptor EasyBag spike                 | ●PUR (Polyurethane)                                                                                               |
| C30700        | ENPlus spike                          | ●ABS (Acrylonitrile-Butadiene-Styrene)<br>●Pigment ABS purple                                                     |
| Packaging     |                                       |                                                                                                                   |
|               | PE-Band 90 x 30 x 0.05 mm             | ●HDPE (high density polyethylene)                                                                                 |
|               | Adhesive tape                         | ●BOPP (biaxially oriented polypropylene) film and rubber adhesive                                                 |
|               | Roll ENFit label 105×148.8 mm         | ●Paper (blank white with violette bar) and Adhesive                                                               |
|               | White paper for IFU printing          | ●Paper                                                                                                            |
|               | Compound foil 90µm                    | ●Multilayer flat film PA (Polyamide) /adhesive layer / PE (Polyethylene)                                          |
|               | Carton box                            | ●Cardboard                                                                                                        |
|               | Peel paper Amika ENFit ISO 100x225 mm | ●Paper                                                                                                            |
| Sterilization |                                       |                                                                                                                   |
|               | Sterilization gas                     | ●Ethylene oxide                                                                                                   |
|               | Indicator tape for EO sterilization   | ●Process indicator tape for Ethylene Oxide (EO) sterilization                                                     |