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| <b>Article code</b>            | 7751904 (M44310008)            |
| <b>Article name acc. DoC</b>   | Amika Varioline Comfort, 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>                                                      |
| C10467       | Roller clamp                                | <ul style="list-style-type: none"> <li>●housing: PP (Polypropylene) plus colourant blue</li> <li>●wheel: HDPE (high density polyethylene)</li> </ul>                        |
| C11503       | Solvent                                     | <ul style="list-style-type: none"> <li>●THF (Tetrahydrofuran), also 1,4-Epoxy butane</li> </ul>                                                                             |
| C30601       | Adaptor                                     | <ul style="list-style-type: none"> <li>●MABS (Methylmethacrylate Acrylonitrile Butadiene Styrene)</li> </ul>                                                                |
| C30844       | ENFit male cap, vented                      | <ul style="list-style-type: none"> <li>●PP (Polypropylene)</li> </ul>                                                                                                       |
| C30931       | Tube 3 x 5 mm                               | <ul style="list-style-type: none"> <li>●PVC (Polyvinylchloride) noDOP with plasitcizer TEHTM (Tri-(2-ethylhexyl) trimellitate)</li> </ul>                                   |
| C30953       | Tube 3.5 x 5.0 mm                           | <ul style="list-style-type: none"> <li>●PVC (Polyvinylchloride) with plasticizer TOTM</li> </ul>                                                                            |
| C60931       | Tube 3 x 5 mm                               | <ul style="list-style-type: none"> <li>●PVC (Polyvinylchloride), plasticizer TOTM, stabiliser calcium / zinc, natural - unpigmented</li> </ul>                              |
| J1010280     |                                             |                                                                                                                                                                             |
| C10275       | Lower part of EN drip chamber for 3.0 x 5.0 | <ul style="list-style-type: none"> <li>●PVC (Polyvinylchloride) transparent, plasticizer TEHTM (Tri-2-ethylhexyl trimellitate; TOTM)</li> </ul>                             |
| C10897       | Sealing for Cross spike                     | <ul style="list-style-type: none"> <li>●LDPE (low density polyethylene) + EPE (foamed PE)</li> </ul>                                                                        |
| C11553       | Solvent                                     | <ul style="list-style-type: none"> <li>●CHN (Cyclohexanone)</li> </ul>                                                                                                      |
| C30478       | Union nut EN                                | <ul style="list-style-type: none"> <li>●PP (Polypropylene) (50 %)</li> <li>●Resin ester polymer (carrier material) + pigment dispersion</li> </ul>                          |
| C30479       | EN Drip chamber upper part                  | <ul style="list-style-type: none"> <li>●ABS (Acrylonitrile-Butadiene-Styrene)</li> <li>●Pigment ABS purple</li> </ul>                                                       |
| J1010767     |                                             |                                                                                                                                                                             |
| C10330       | Air ventilation plug                        | <ul style="list-style-type: none"> <li>●ABS (Acrylonitrile Butadiene Styrene)</li> <li>●Colourant white, ABS (Acrylonitrile Butadiene Styrene)-carrier</li> </ul>           |
| C10824       | Bacteria filter                             | <ul style="list-style-type: none"> <li>●glass microfiber filter</li> </ul>                                                                                                  |
| C10825       | Bacteria filter band                        | <ul style="list-style-type: none"> <li>●hydrophobic glass microfibre</li> </ul>                                                                                             |
| C11120       | Lid valve                                   | <ul style="list-style-type: none"> <li>●Silicone</li> </ul>                                                                                                                 |
| C30032       | Insert ENPlus                               | <ul style="list-style-type: none"> <li>●HDPE (high density polyethylene)</li> <li>●Colourant lilac</li> </ul>                                                               |
| C30058       | Body Varioline Adapter ENPlus               | <ul style="list-style-type: none"> <li>●LDPE (low density polyethylene)</li> <li>●PE (Polyethylene)</li> <li>●Colourant lilac</li> <li>●lubricant demoulding aid</li> </ul> |

| Article code | Article name                   | Material                                                                                                                        |
|--------------|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| J1040189     |                                |                                                                                                                                 |
| 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                                                                                         |
| C30820       | ENPlus spike                   | ●ABS (Acrylonitrile Butadiene Styrene)<br>●Carrier: Novodur P2H-AT<br>●Components: Inorganic and organic pigments               |
| C41134       | Drip chamber                   | ●cap and lower part: SBC (Styrene Butadiene Copolymer)<br>●glue: THF (Tetrahydrofuran)<br>●adaptor for tube: PUR (Polyurethane) |
| 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       | ●HDPE (high density polyethylene)<br>●colourbatch purple                                                                        |
| C30298       | ENFit stopcock housing FK      | ●Copolyester (BPA-free)                                                                                                         |
| C30823       | ENFit female cap               | ●HDPE (high density Polyethylene)<br>●colourant violet                                                                          |
| C30878       | ENFit Stopcock 5.0 mm (open)   | ●housing: Copolyester (BPA-free)<br>●handle: HDPE (high density polyethylene) with colourant<br>●PDMS (Polydimethylsiloxane)    |
| 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            | ●Copolyester (BPA-free)<br>●RAL 4005 (violet), Colour concentrate                                                               |
| C30953       | Tube 3.5 x 5.0 mm              | ●PVC (Polyvinylchloride) with plasticizer TOTM                                                                                  |
| J1040285     |                                |                                                                                                                                 |
| 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                                                                                         |
| C30700       | ENPlus spike                   | ●ABS (Acrylonitrile-Butadiene-Styrene)<br>●Pigment ABS purple                                                                   |

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|---------------|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| C41134        | Drip chamber                              | <ul style="list-style-type: none"> <li>● cap and lower part: SBC (Styrene Butadiene Copolymer)</li> <li>● glue: THF (Tetrahydrofuran)</li> <li>● adaptor for tube: PUR (Polyurethane)</li> </ul> |
| J1040286      |                                           |                                                                                                                                                                                                  |
| C10333        | Air ventilation plug                      | <ul style="list-style-type: none"> <li>● ABS (Acrylonitrile-Butadiene-Styrene)</li> <li>● Colourant white, ABS (Acrylonitrile-Butadiene-Styrene)-carrier</li> </ul>                              |
| C10824        | Bacteria filter                           | <ul style="list-style-type: none"> <li>● glass microfiber filter</li> </ul>                                                                                                                      |
| C11120        | Lid valve                                 | <ul style="list-style-type: none"> <li>● Silicone</li> </ul>                                                                                                                                     |
| C30032        | Insert ENPlus                             | <ul style="list-style-type: none"> <li>● HDPE (high density polyethylene)</li> <li>● Colourant lilac</li> </ul>                                                                                  |
| C30058        | Body Varioline Adapter ENPlus             | <ul style="list-style-type: none"> <li>● LDPE (low density polyethylene)</li> <li>● PE (Polyethylene)</li> <li>● Colourant lilac</li> <li>● lubricant demoulding aid</li> </ul>                  |
| Packaging     |                                           |                                                                                                                                                                                                  |
|               | Tubular foil for packaging                | <ul style="list-style-type: none"> <li>● Film 500m x 350 mm x 40 µm</li> <li>● Mixture of different Polyolefines PE (Polyethylene), LDPE (Polyethylene, low density), transparent</li> </ul>     |
|               | PE-Band 90 x 30 x 0.05 mm                 | <ul style="list-style-type: none"> <li>● HDPE (high density polyethylene)</li> </ul>                                                                                                             |
|               | Adhesive tape                             | <ul style="list-style-type: none"> <li>● BOPP (biaxially oriented polypropylene) film and rubber adhesive</li> </ul>                                                                             |
|               | Roll ENFit label 105×148.8 mm             | <ul style="list-style-type: none"> <li>● Paper (blank white with violette bar) and Adhesive</li> </ul>                                                                                           |
|               | White paper for IFU printing              | <ul style="list-style-type: none"> <li>● Paper</li> </ul>                                                                                                                                        |
|               | Carton 397 x 230 x 205 mm                 | <ul style="list-style-type: none"> <li>● Paper</li> </ul>                                                                                                                                        |
|               | Compound foil 90µm                        | <ul style="list-style-type: none"> <li>● Multilayer flat film PA (Polyamide) /adhesive layer / PE (Polyethylene)</li> </ul>                                                                      |
|               | peel paper Amika Sets ENFit ISO 100x225mm | <ul style="list-style-type: none"> <li>● Paper 60 g/m<sup>2</sup></li> </ul>                                                                                                                     |
| Sterilization |                                           |                                                                                                                                                                                                  |
|               | Sterilization gas                         | <ul style="list-style-type: none"> <li>● Ethylene oxide</li> </ul>                                                                                                                               |
|               | Indicator tape for EO sterilization       | <ul style="list-style-type: none"> <li>● Process indicator tape for Ethylene Oxide (EO) sterilization</li> </ul>                                                                                 |