



LIST of

medical devices which are labelled for DEHP, as of 21 March 2010, according to Medical Device Directive (93/42/EEC as amended by 2007/47/EC)

AND

devices which are NOT labelled for DEHP according to Medical Device Directive, but which do contain DEHP in a concentration > 0,1% w/w or do contain other SVHC in a concentration > 0,1% w/w, including packaging

| Product code | Product description | SVHC identification |
|-------------------------------|--|---|
| Hospital products | | |
| Infusion Set | | |
| TS+PM351 | Terufusion Infusion Set | Labelled for DEHP according MDD 93/42/EEC |
| Blood Pressure Monitor | | |
| XX*ES11L04 | Blood pressure cuff for ES-H55, large, latex-free | DEHP |
| XX*ES11M04 | Blood pressure cuff for ES-H55, medium, latex-free | DEHP |
| XX*ES11S04 | Blood pressure cuff for ES-H55, small, latex-free | DEHP |
| XX*ES11SS04 | Blood pressure cuff for ES-H55, extra small, latex-free | DEHP |
| IS products | | |
| Aspiration Catheter | | |
| EG... | Eliminate | Labelled for DEHP according MDD 93/42/EEC until lot number K1112-00350-00 |
| | Note: as from lot number K1112-00350-00, Eliminate items are DEHP-free and are not labelled for DEHP anymore | |
| Progreat | | |
| MC-PP..... | Progreat (with guide wire) | DEHP |
| MC-PE..... | Progreat (with guide wire) | DEHP |
| Radifocus Guide Wire M | | |
| RF-GA.....M | | DEHP |
| RF-GS.....M | | DEHP |
| RF-PA.....M | | DEHP |
| RF-PS.....M | | DEHP |
| RF*GA.....M | | DEHP |
| RF*GB.....M | | DEHP |
| RF*GE.....M | | DEHP |
| RF*GR.....M | | DEHP |
| RF*GS.....M | | DEHP |
| RF*HN.....M | | DEHP |
| RF*HR.....M | | DEHP |
| RF*PA.....M | | DEHP |
| RF*PS.....M | | DEHP |
| RF*RA.....M | | DEHP |
| RF*RB.....M | | DEHP |



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| Product code | Product description | SVHC identification |
|--|--|--|
| RE*GK.....M | | DEHP |
| RE*GL.....M | | DEHP |
| RF+GA.....M | | DEHP |
| RF+GS.....M | | DEHP |
| RF+PA.....M | | DEHP |
| Radifocus Glidewire Advantage | | |
| RA*CA.....CM | | DEHP |
| RA*CS.....CM | | DEHP |
| RA*FA.....CM | | DEHP |
| RA*FS.....CM | | DEHP |
| Radifocus Guide Wire M Non-vascular | | |
| NV-GA.....M | | DEHP |
| NV-GS.....M | | DEHP |
| NV-PA.....M | | DEHP |
| NV-PS.....M | | DEHP |
| Radifocus Guide Wire GT with gold coil | | |
| RG*G.....M | | DEHP |
| Crosswire NT - PTCA guide wire | | |
| CW*NA.....M | | DEHP |
| Crosswire - PTCA guide wire | | |
| CW*NS.....M | | DEHP |
| SoloPath Balloon Expandable Transfemoral Introducer | | |
| STFI-1425 | Note: as from lot number W035632, Solopath items are DEHP-free and are not labelled for DEHP anymore | Labelled for DEHP according MDD 93/42/EEC until lot number W035632 |
| STFI-1435 | | |
| STFI-1825 | | |
| STFI-1835 | | |
| STFI-1925 | | |
| STFI-1935 | | |
| STFI-2125 | | |
| STFI-2135 | | |



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| Product code | Product description | SVHC identification |
|---------------------------------|--|---|
| Cardiovascular products | | |
| Cannulae & Catheters | | |
| 816502 | Retrograde Cardioplegia Cannula, auto-inflating, smooth balloon, rigid insertion stylet, Sure-Touch® handle, 10,5" length, 15Fr | Labelled for DEHP according MDD 93/42/EEC |
| 816502L | Retrograde Cardioplegia Cannula, auto-inflating, smooth balloon, rigid insertion stylet, Sure-Touch® handle, 12,5" length, 15Fr | Labelled for DEHP according MDD 93/42/EEC |
| 816504 | Retrograde Cardioplegia Cannula, auto-inflating, textured balloon, rigid insertion stylet, Sure-Touch® handle, 10,5" length, 15Fr | Labelled for DEHP according MDD 93/42/EEC |
| 816504L | Retrograde Cardioplegia Cannula, auto-inflating, textured balloon, rigid insertion stylet, Sure-Touch® handle, 12,5" length, 15Fr | Labelled for DEHP according MDD 93/42/EEC |
| 816505 | Retrograde Cardioplegia Cannula, auto-inflating, smooth balloon, rigid insertion stylet, 10,5" length, 15Fr | Labelled for DEHP according MDD 93/42/EEC |
| 816506 | Retrograde Cardioplegia Cannula, auto-inflating, smooth balloon, guidewire insertion stylet, 10,5" length, 15Fr | Labelled for DEHP according MDD 93/42/EEC |
| 820355 | Retrograde Cardioplegia Cannula, manually inflating, smooth balloon, guidewire insertion stylet, 15Fr | Labelled for DEHP according MDD 93/42/EEC |
| 820356 | Retrograde Cardioplegia Cannula, manually inflating, textured balloon, guidewire insertion stylet, stopcock in pressure line, 15Fr | Labelled for DEHP according MDD 93/42/EEC |
| 820357 | Retrograde Cardioplegia Cannula, manually inflating, smooth balloon, rigid insertion stylet, 15Fr | Labelled for DEHP according MDD 93/42/EEC |
| 824364 | Perfusion set, straight with capped vent, 5" length | Labelled for DEHP according MDD 93/42/EEC |
| 824365 | Perfusion set, re-circulation, Y-type with capped vent, 8" length with color-coded clamps | Labelled for DEHP according MDD 93/42/EEC |
| 824366 | Perfusion set, venting, Y-type, 7,5" length with color-coded clamps | Labelled for DEHP according MDD 93/42/EEC |
| 824367 | Multiple Perfusion set, 15" length, one 3" arm, three 10" arms, color-coded clamps, male luer locks, female infusion connector | Labelled for DEHP according MDD 93/42/EEC |
| 824368 | Multiple Perfusion set with vent line, 15" length, color-coded clamps, male luer locks, female infusion connector | Labelled for DEHP according MDD 93/42/EEC |
| 824369 | Perfusion set, coronary perfusion, Y-type, 13,5" length | Labelled for DEHP according MDD 93/42/EEC |
| 824370 | Perfusion cannula, free-flow, 3mm blunt tip | Labelled for DEHP according MDD 93/42/EEC |
| A2006 | Arterial cannula, non-reinforced, curved tip with flange, without connector, 20Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A2406 | Arterial cannula, non-reinforced, curved tip with flange, without connector, 24Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A20061V | Arterial cannula, non-reinforced, curved tip with flange, with connector, with vent plug, 20Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A22061V | Arterial cannula, non-reinforced, curved tip with flange, with connector, with vent plug, 22Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A24061V | Arterial cannula, non-reinforced, curved tip with flange, with connector, with vent plug, 24Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A20062V | Arterial cannula, non-reinforced, curved tip with flange, with luer connector, with vent plug, 20Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A22062V | Arterial cannula, non-reinforced, curved tip with flange, with luer connector, with vent plug, 22Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A24062V | Arterial cannula, non-reinforced, curved tip with flange, with luer connector, with vent plug, 24Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A2216 | Arterial cannula, reinforced, curved tip with flange, 22Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| B2216 | Arterial cannula, reinforced, curved tip with flange, 22Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| A2416 | Arterial cannula, reinforced, curved tip with flange, 24Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| B2416 | Arterial cannula, reinforced, curved tip with flange, 24Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| A20161V | Arterial cannula, reinforced, curved tip with flange, with connector, with vent plug, 20Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |



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|--------------|---|---|
| A22161V | Arterial cannula, reinforced, curved tip with flange, with connector, with vent plug, 22Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| A24161V | Arterial cannula, reinforced, curved tip with flange, with connector, with vent plug, 24Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| A20162V | Arterial cannula, reinforced, curved tip with flange, with luer connector, with vent plug, 20Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| A22162V | Arterial cannula, reinforced, curved tip with flange, with luer connector, with vent plug, 22Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| A24162V | Arterial cannula, reinforced, curved tip with flange, with luer connector, with vent plug, 24Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| A2003 | Arterial cannula, non-reinforced, straight tip with ring, without connector, 20Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A2203 | Arterial cannula, non-reinforced, straight tip with ring, without connector, 22Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A2403 | Arterial cannula, non-reinforced, straight tip with ring, without connector, 24Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A20031 | Arterial cannula, non-reinforced, straight tip with ring, with connector, 20Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A20031V | Arterial cannula, non-reinforced, straight tip with ring, with connector, with vent plug, 20Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A22031V | Arterial cannula, non-reinforced, straight tip with ring, with connector, with vent plug, 22Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A24031V | Arterial cannula, non-reinforced, straight tip with ring, with connector, with vent plug, 24Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A20032 | Arterial cannula, non-reinforced, straight tip with ring, with luer connector, 20Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A22032V | Arterial cannula, non-reinforced, straight tip with ring, with luer connector, with vent plug, 22Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A24032V | Arterial cannula, non-reinforced, straight tip with ring, with luer connector, with vent plug, 24Fr, 22cm | Labelled for DEHP according MDD 93/42/EEC |
| A2013 | Arterial cannula, reinforced, straight tip with ring, without connector, 20Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| A2013V | Arterial cannula, reinforced, straight tip with ring, without connector, with vent plug, 20Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| B2013 | Arterial cannula, reinforced, straight tip with ring, without connector, 20Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| B2013V | Arterial cannula, reinforced, straight tip with ring, without connector, with vent plug, 20Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| A20131 | Arterial cannula, reinforced, straight tip with ring, with connector, 20Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| A20131V | Arterial cannula, reinforced, straight tip with ring, with connector, with vent plug, 20Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| B20131V | Arterial cannula, reinforced, straight tip with ring, with connector, with vent plug, 20Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| A22131V | Arterial cannula, reinforced, straight tip with ring, with connector, with vent plug, 22Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| A24131V | Arterial cannula, reinforced, straight tip with ring, with connector, with vent plug, 24Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| A20132 | Arterial cannula, reinforced, straight tip with ring, with luer connector, 20Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| A20132V | Arterial cannula, reinforced, straight tip with ring, with luer connector, with vent plug, 20Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| A22132V | Arterial cannula, reinforced, straight tip with ring, with luer connector, with vent plug, 22Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| A24132V | Arterial cannula, reinforced, straight tip with ring, with luer connector, with vent plug, 24Fr, 30cm | Labelled for DEHP according MDD 93/42/EEC |
| AC2013 | Aortic catheter, reinforced, straight tip with ring, 20Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| AC2213 | Aortic catheter, non-reinforced, straight tip with ring, 22Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| AC2413 | Aortic catheter, non-reinforced, straight tip with ring, 24Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| AC201341 | Aortic catheter, non-reinforced, straight tip with ring, with connector, 20Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |



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|--------------|--|---|
| AC201341V | Aortic catheter, non-reinforced, straight tip with ring, with connector, with vent plug, 20Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| AC221341V | Aortic catheter, non-reinforced, straight tip with ring, with connector, with vent plug, 22Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| AC241341 | Aortic catheter, non-reinforced, straight tip with ring, with connector, 24Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| AC241341V | Aortic catheter, non-reinforced, straight tip with ring, with connector, with vent plug, 24Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| AC261341V | Aortic catheter, non-reinforced, straight tip with ring, with connector, with vent plug, 26Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| AC301341V | Aortic catheter, non-reinforced, straight tip with ring, with connector, with vent plug, 30Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| AC201342V | Aortic catheter, non-reinforced, straight tip with ring, with luer connector, with vent plug, 20Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| AC221342V | Aortic catheter, non-reinforced, straight tip with ring, with luer connector, with vent plug, 22Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| AC241342V | Aortic catheter, non-reinforced, straight tip with ring, with luer connector, with vent plug, 24Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| AC261342V | Aortic catheter, non-reinforced, straight tip with ring, with luer connector, with vent plug, 26Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| AC301342V | Aortic catheter, non-reinforced, straight tip with ring, with luer connector, with vent plug, 30Fr, 21cm | Labelled for DEHP according MDD 93/42/EEC |
| V2018 | Venous catheter, reinforced with bullet tip, straight, 20Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| V2618 | Venous catheter, reinforced with bullet tip, straight, 20Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| V3218 | Venous catheter, reinforced with bullet tip, straight, 26Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| V3418 | Venous catheter, reinforced with bullet tip, straight, 34Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| V3618 | Venous catheter, reinforced with bullet tip, straight, 36Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| V4018 | Venous catheter, reinforced with bullet tip, straight, 40Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| V2019 | Venous catheter, reinforced with bullet tip, right angled 90°, 20Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| V2619 | Venous catheter, reinforced with bullet tip, right angled 90°, 26Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| V3219 | Venous catheter, reinforced with bullet tip, right angled 90°, 32Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| V3419 | Venous catheter, reinforced with bullet tip, right angled 90°, 34Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| V3619 | Venous catheter, reinforced with bullet tip, right angled 90°, 36Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| V4019 | Venous catheter, reinforced with bullet tip, right angled 90°, 40Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V321L8 | Flex Line Venous catheter, reinforced with lighthouse tip, straight, 32Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V361L8 | Flex Line Venous catheter, reinforced with lighthouse tip, straight, 36Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V321L9 | Flex Line Venous catheter, reinforced with lighthouse tip, right angled 90°, 32Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V361L9 | Flex Line Venous catheter, reinforced with lighthouse tip, right angled 90°, 36Fr, 39cm | Labelled for DEHP according MDD 93/42/EEC |
| V360510 | Two Stage Venous catheter, non-reinforced, without connector, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V3605101 | Two Stage Venous catheter, non-reinforced, with connector, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V3605102 | Two Stage Venous catheter, non-reinforced, with luer connector, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V361510 | Two Stage Venous catheter, distal reinforced, without connector, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V3615101 | Two Stage Venous catheter, distal reinforced, with connector, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |



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| Product code | Product description | SVHC identification |
|--------------|---|---|
| V3615102 | Two Stage Venous catheter, distal reinforced, with luer connector, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V360511 | Two Stage Venous catheter, proximal reinforced with rigid tip, without connector, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V360511FB | Two Stage Venous catheter, proximal reinforced with rigid tip, without connector, 36/51Fr, 40cm, flat body | Labelled for DEHP according MDD 93/42/EEC |
| V3605111 | Two Stage Venous catheter, proximal reinforced with rigid tip, with connector, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V3605111FB | Two Stage Venous catheter, proximal reinforced with rigid tip, with connector, 36/51Fr, 40cm, flat body | Labelled for DEHP according MDD 93/42/EEC |
| V3605112 | Two Stage Venous catheter, proximal reinforced with rigid tip, with luer connector, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V321401 | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, without connector, 32/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V321401FB | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, without connector, 32/40Fr, 40cm, flat body | Labelled for DEHP according MDD 93/42/EEC |
| V341401 | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, without connector, 34/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V341401FB | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, without connector, 34/40Fr, 40cm, flat body | Labelled for DEHP according MDD 93/42/EEC |
| V361511FB | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, without connector, 36/51Fr, 40cm, flat body | Labelled for DEHP according MDD 93/42/EEC |
| V3214011 | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, with connector, 32/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V3214011FB | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, with connector, 32/40Fr, 40cm, flat body | Labelled for DEHP according MDD 93/42/EEC |
| V3414011 | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, with connector, 34/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V3414011FB | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, with connector, 34/40Fr, 40cm, flat body | Labelled for DEHP according MDD 93/42/EEC |
| V3615111 | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, with connector, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V3615111FB | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, with connector, 36/51Fr, 40cm, flat body | Labelled for DEHP according MDD 93/42/EEC |
| V3214012 | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, with luer connector, 32/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V3214012FB | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, with luer connector, 32/40Fr, 40cm, flat body | Labelled for DEHP according MDD 93/42/EEC |
| V3414012 | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, with luer connector, 34/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V3414012FB | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, with luer connector, 34/40Fr, 40cm, flat body | Labelled for DEHP according MDD 93/42/EEC |
| V3615112 | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, with luer connector, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| V3615112FB | Two Stage Venous catheter, proximal and distal reinforced with rigid tip, with luer connector, 36/51Fr, 40cm, flat body | Labelled for DEHP according MDD 93/42/EEC |
| 01V32L40 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, without connector, with standard body, 32/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V32L40FB | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, without connector, with flat body, 32/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V34L46 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, without connector, with standard body, 34/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V34L46FB | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, without connector, with flat body, 34/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V36L46 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, without connector, with standard body, 36/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V36L46FB | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, without connector, with flat body, 36/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V36L51 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, without connector, with standard body, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V36L51FB | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, without connector, with flat body, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V32L401 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with connector, with standard body, 32/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |



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|--------------|--|---|
| 01V32L401FB | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with connector, with flat body, 32/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V34L461 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with connector, with standard body, 34/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V34L461FB | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with connector, with flat body, 34/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V36L461 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with connector, with standard body, 36/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V36L461FB | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with connector, with flat body, 36/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V36L511 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with connector, with standard body, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V36L511FB | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with connector, with flat body, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V32L402 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with luer lock, with standard body, 32/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V32L402FB | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with luer lock, with flat body, 32/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V34L462 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with luer lock, with standard body, 34/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V34L462FB | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with luer lock, with flat body, 34/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V36L462 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with luer lock, with standard body, 36x46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V36L462FB | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with luer lock, with flat body, 36x46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V36L512 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with luer lock, with standard body, 36x51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V36L512FB | Flex Line Two Stage Venous catheter, proximal and distal reinforced with lighthouse tip, with luer lock, with flat body, 36x51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V34140 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with bullet tip, without connector, with standard body, 34/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V34146 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with bullet tip, without connector, with standard body, 34/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V36146 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with bullet tip, without connector, with standard body, 36/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V36151 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with bullet tip, without connector, with standard body, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V341401 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with bullet tip, with connector, with standard body, 34/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V341461 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with bullet tip, with connector, with standard body, 34/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V361461 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with bullet tip, with connector, with standard body, 36/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V361511 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with bullet tip, with connector, with standard body, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V341402 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with bullet tip, with luer lock, with standard body, 34/40Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V341462 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with bullet tip, with luer lock, with standard body, 34/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V361462 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with bullet tip, with luer lock, with standard body, 36/46Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| 01V361512 | Flex Line Two Stage Venous catheter, proximal and distal reinforced with bullet tip, with luer lock, with standard body, 36/51Fr, 40cm | Labelled for DEHP according MDD 93/42/EEC |
| ARC01 | Aortic root cannula, non-vented, 14G needle, 10Fr, 15cm | Labelled for DEHP according MDD 93/42/EEC |
| ARC05 | Aortic root cannula, vented, 16G needle, 8Fr, 15cm | Labelled for DEHP according MDD 93/42/EEC |
| ARC02 | Aortic root cannula, vented, 14G needle, 10Fr, 15cm | Labelled for DEHP according MDD 93/42/EEC |
| VC3 | Vessel cannula, 1Fr | Labelled for DEHP according MDD 93/42/EEC |
| VC3B | Vessel cannula with closed back check valve, 1Fr | Labelled for DEHP according MDD 93/42/EEC |



LIST of

medical devices which are labelled for DEHP, as of 21 March 2010, according to Medical Device Directive (93/42/EEC as amended by 2007/47/EC)

AND

devices which are NOT labelled for DEHP according to Medical Device Directive, but which do contain DEHP in a concentration > 0,1% w/w or do contain other SVHC in a concentration > 0,1% w/w, including packaging

| Product code | Product description | SVHC identification |
|---|---|---|
| FS300 | Flexible sucker, 17Fr, 35cm | Labelled for DEHP according MDD 93/42/EEC |
| SX Oxygenators (TCVS) | | |
| CX*SX10RX03 | Capiox SX 10 Oxygenator, hardshell Reservoir, X-coating, Purge line | DEHP |
| CX*SX18... | Capiox SX 18 Oxygenator | Labelled for DEHP according MDD 93/42/EEC |
| CX*SX25... | Capiox SX 25 Oxygenator | Labelled for DEHP according MDD 93/42/EEC |
| CX*SXRX | Capiox Oxygenator Hardshell Reservoir | Labelled for DEHP according MDD 93/42/EEC |
| CDI H/S Cuvettes with extension tubing | | |
| 6932 | 1/2" cuvette with 6" extension tubing | Labelled for DEHP according MDD 93/42/EEC |
| 6933 | 3/8" cuvette with 6" extension tubing | Labelled for DEHP according MDD 93/42/EEC |
| 6934 | 1/4" cuvette with 6" extension tubing | Labelled for DEHP according MDD 93/42/EEC |
| Sarns Myo Cardioplegia Delivery Sets | | |
| 15486 | MP4 Clear with cannulation and recirculation | Labelled for DEHP according MDD 93/42/EEC |
| 15501 | MP4 Clear with module and recirculation | Labelled for DEHP according MDD 93/42/EEC |
| 16010 | MP4 Blood set, 4:1 ratio, no recirculation | Labelled for DEHP according MDD 93/42/EEC |
| 16015 | MP4 Clear filter module and recirculation | Labelled for DEHP according MDD 93/42/EEC |
| 16110 | Infuse line for clear MP4 sets | Labelled for DEHP according MDD 93/42/EEC |
| 16130 | Infuse line for blood sets | Labelled for DEHP according MDD 93/42/EEC |
| 16200 | MP4 Blood set, 2:1 ratio, no recirculation | Labelled for DEHP according MDD 93/42/EEC |
| 165720 | Conducer/MP4 set, 4:1 ratio, no recirculation | Labelled for DEHP according MDD 93/42/EEC |
| 5852 | Low prime CP set, 4:1 ratio, no recirculation | Labelled for DEHP according MDD 93/42/EEC |
| 6376 | Conducer/TPBT, 4:1 ratio, bridged | Labelled for DEHP according MDD 93/42/EEC |
| Tubing Sets | | |
| Note: Customer-requested tubing sets are not mentioned in this list, as the customer is aware of the DEHP content, based on the mutually agreed drawing/configuration. | | |
| CX-FAC01 | Tubing set, vacuum assisted venous drainage kit | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC02 | Tubing | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC03 | Tubing | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC03X | Tubing, X-coated | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC04 | Tubing | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC06 | Tubing | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC64 | Extension line | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC65 | Extension line | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC75 | Pressure line | Labelled for DEHP according MDD 93/42/EEC |



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AND

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| Product code | Product description | SVHC identification |
|--------------|--------------------------------|---|
| CX-FAC76 | 4L reservoir with SX18R | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC97 | CPG table line | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC100 | Drainage bag | DEHP |
| CX-FAC101 | HC to drainage bag adaptor | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC102 | RAP bag | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC103 | RAP bag | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC104 | RAP bag | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC105 | RAP bag | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC106 | 1/2 Pump line | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC107 | 3/8 Pump line | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC108 | 1/4 Pump line | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC110 | 200 cm 3/8 PVC spare tubing | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC111 | 200 cm 1/4 PVC spare tubing | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC112 | 1/2 PVC spare tubing | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC114 | Pressure monitoring kit | Labelled for DEHP according MDD 93/42/EEC |
| CX-FAC115 | 200 cm 1/4 x 3/32 spare tubing | Labelled for DEHP according MDD 93/42/EEC |
| 688694 | Pressure monitoring kit | Labelled for DEHP according MDD 93/42/EEC |
| CX-FCP21 | Blood Cardioplegia System | Labelled for DEHP according MDD 93/42/EEC |
| CX-FCP22 | Blood Cardioplegia System | Labelled for DEHP according MDD 93/42/EEC |
| CX-FCP41 | Blood Cardioplegia System | Labelled for DEHP according MDD 93/42/EEC |
| CX-FCP42 | Blood Cardioplegia System | Labelled for DEHP according MDD 93/42/EEC |
| CX-FHC01 | Pre-connected HC | Labelled for DEHP according MDD 93/42/EEC |
| CX-FHC02 | Pre-connected HC | Labelled for DEHP according MDD 93/42/EEC |
| CX-FHC12 | Pre-connected HC | Labelled for DEHP according MDD 93/42/EEC |
| HPH400TS | HPH400 Hemoconcentrator set | Labelled for DEHP according MDD 93/42/EEC |
| HPH700TS | HPH700 Hemoconcentrator set | Labelled for DEHP according MDD 93/42/EEC |
| HPH1000TS | HPH1000 Hemoconcentrator set | Labelled for DEHP according MDD 93/42/EEC |
| CX-ROC25AL6 | ROCsafesRX | Labelled for DEHP according MDD 93/42/EEC |
| CX-ROC25AL6X | ROCsafesRX | Labelled for DEHP according MDD 93/42/EEC |
| CX-ROC25AL8X | ROCsafesRX | Labelled for DEHP according MDD 93/42/EEC |
| CX-ROCFX15 | ROCsafesFX | Labelled for DEHP according MDD 93/42/EEC |
| CX-ROCFX25 | ROCsafesFX | Labelled for DEHP according MDD 93/42/EEC |



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AND

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| Product code | Product description | SVHC identification |
|----------------|---|---|
| CX-ROCA | ROCsafe accessory pack | Labelled for DEHP according MDD 93/42/EEC |
| CX-ROCB | ROCsafe accessory pack | Labelled for DEHP according MDD 93/42/EEC |
| CX-ROCC | ROCsafe accessory pack | Labelled for DEHP according MDD 93/42/EEC |
| CX-ROCG | ROCsafe accessory pack | Labelled for DEHP according MDD 93/42/EEC |
| CX-ROCH | ROCsafe accessory pack | Labelled for DEHP according MDD 93/42/EEC |
| CX-ROCRXAL6 | ROCsafeRX | Labelled for DEHP according MDD 93/42/EEC |
| CX-ROCRXAL6X | ROCsafeRX | Labelled for DEHP according MDD 93/42/EEC |
| CX-ROCRXAL8X | ROCsafeRX | Labelled for DEHP according MDD 93/42/EEC |
| Filters | | |
| AV6SVB | AutoVent SV Arterial Blood Filter | Labelled for DEHP according MDD 93/42/EEC |
| LG6B | LeukoGuard LG Leucocyte Reduction Arterial Blood Filter | Labelled for DEHP according MDD 93/42/EEC |
| AL8B | Arterial Blood Filter | Labelled for DEHP according MDD 93/42/EEC |
| AL8S | Arterial Blood Filter | Labelled for DEHP according MDD 93/42/EEC |
| AL6B | Arterial Blood Filter | Labelled for DEHP according MDD 93/42/EEC |
| AL3B | Paediatric Arterial Blood Filter | Labelled for DEHP according MDD 93/42/EEC |
| AL3S | Paediatric Arterial Blood Filter | Labelled for DEHP according MDD 93/42/EEC |
| BC2B | LeukoGuard BC2 Blood Cardioplegia Filter | Labelled for DEHP according MDD 93/42/EEC |
| RS1VAE | LeukoGuard RS Leucocyte Removal Filter with attached set for salvaged blood | Labelled for DEHP according MDD 93/42/EEC |
| SB1KLE | LipiGuard SB Reinfusion Set for Salvaged Blood | Labelled for DEHP according MDD 93/42/EEC |