

Certificato di conformità CE

EC Certificate of Conformity



Garanzia di qualità della produzione secondo la direttiva 93/42/CEE allegato V
EC Directive 93/42/EEC Annex V Production Quality Assurance Medical Devices

Certificato n°: DD 60133728

Registration No:

Fabbricante: BHL – MEDICAL INDUSTRIA DE PRODUTOS HOSPITALARES,
Manufacturer: LDA

Sede legale: Estrada de Avessada, 390
Registered Headquarter: 2665-402 Santò Estevão Galés – Portugal

Sede operativa: Estrada de Avessada, 390
Operational Headquarter: 2665-402 Santò Estevão Galés – Portugal

Scopo: Dispositivi non attivi per iniezione ed infusione / *Non-active devices*
Scope: *for injection and infusion*

(Vedere allegato tecnico al presente Certificato per tipologie, modelli e codici)
(See the attachment for typologies, models and codes designation)

L'organismo notificato dichiara che il Sistema di qualità stabilito ed applicato dalla società sopra specificata soddisfa i requisiti dell'allegato V della suddetta direttiva. Questa approvazione è soggetta a sorveglianza periodica, così come definita nell'allegato V, articolo 4 della suddetta direttiva e può essere utilizzata congiuntamente alla dichiarazione di conformità redatta dal fabbricante. / *The Notified Body hereby declares that the requirements of annex V of the Directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned Directive and can be used in conjunction with the conformity declaration issued by the Manufacturer.*

L'organismo notificato/ Notified Body

Data di emissione/Issue date: 11/12/2018

Data di ultima modifica/Last revision date: 30/07/2020

Data di scadenza/Expiry date: 10/12/2023



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TÜV Rheinland Italia S.r.l. - Via Mattei, 3 - 20010 - Pogliano Milanese (MI)

Autorizzata dal Ministero della Salute e dal Ministero dello Sviluppo Economico
Accredited by Ministry of Health and by Ministry of Economic Development

Organismo notificato con il numero 1936 presso la Commissione Europea
Notified under No. 1936 to the EC Commission

CE La marcatura CE può essere apposta esclusivamente se vengono soddisfatti i requisiti di tutte le direttive CE applicabili **CE**
The CE marking may be used if all relevant and effective EC Directives are complied with

Fabbricante/Manufacturer: BHL – Medical industria de produtos hospitalares, Lda

Scopo/Scope: **Dispositivi non attivi per iniezione ed infusione / Non-active devices for injection and infusion**

Tipologia/ Typology: **Contrast media systems and accessories**

Marca/ Brand name:

Transset Mono Syringe

Modello/ Model:

Transset Mono syringe Contrast filling & injection set

Codici/ Codes:

PR-20197

Marca/ Brand name:

Transset Duo syringe

Modello/ Model:

Transset duo syringe Contrast filling & injection set

Codici/ Codes:

PR-20198

Marca/ Brand name:

Transset Duo syringe in spiral

Modello/ Model:

Transset duo syringe Contrast filling & injection set in spiral

Codici/ Codes:

PR-30510

Marca/ Brand name:

Transset Duo syringe – MRI

Modello/ Model:

Transset duo syringe Contrast filling & injection set for MRI

Codici/ Codes:

PR-20194

Data di ultima modifica: 30/07/2020
Last revision date:

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Marca/ Brand name:

Transset Duo syringe – MRI in spiral

Modello/ Model:

Transset duo syringe Contrast filling & injection set for MRI in spiral

Codici/ Codes:

PR-30511

Marca/ Brand name:

BHL-Single flow

Modello/ Model:

Extensive spiral line with 1 check valve – 1,50m

Extensive spiral line with 1 check valve – 2,00m

Extensive spiral line with 2 check valve – 1,50m

Extensive spiral line with 2 check valve – 2,00m

Extensive line with check valve and LLMM – 0,20m

Extensive line with check valve and LLMM – 0,30m

Extensive line with check valve and LLMM – 0,60m

Extensive line with check valve and LLMM – 1,20m

Extensive line with check valve and LLMM – 1,50m

Extensive line with check valve and LLMM – 2,00m

Extensive line with check valve and LLMM – 2,50m

Extensive line with double check valve and LLMM – 0,20m

Extensive line with double check valve and LLMM – 0,30m

Extensive line with double check valve and LLMM – 0,60m

Extensive line with double check valve and LLMM – 1,20m

Extensive line with double check valve and LLMM – 1,50m

Extensive line with double check valve and LLMM – 2,00m

Extensive line with double check valve and LLMM – 2,50m

Codici/ Codes:

BHL-SVC-150, BHL-SVC-200, BHL-DVC-150, BHL-DVC-200, BHL-SVM-20, BHL-SVM-30, BHL-SVM-60, BHL-SVM-120, BHL-SVM-150, BHL-SVM-200, BHL-SVM-250, BHL-DVM-20, BHL-DVM-30, BHL-DVM-60, BHL-DVM-120, BHL-DVM-150, BHL-DVM-200, BHL-DVM-250

Data di ultima modifica: 30/07/2020

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Marca/ Brand name:

Contrast line for bilateral phlebography

Modello/ Model:

Extensive line with double check valve – VARD – 0,80m

Codici/ Codes:

3302VY14

Marca/ Brand name:

Transflux CT 20

Modello/ Model:

Transflux CT 20 – CT/MRI Contrast connection line

Codici/ Codes:

PR-20199

Marca/ Brand name:

Transflux CT 45

Modello/ Model:

Transflux CT 45 – CT/MRI Contrast connection line

Codici/ Codes:

PR-21379

Marca/ Brand name:

Transflux CT 60

Modello/ Model:

Transflux CT 60 – CT/MRI Contrast connection line

Codici/ Codes:

PR-20201

Marca/ Brand name:

Transflux CT 100

Modello/ Model:

Transflux CT 100 – CT/MRI Contrast connection line

Codici/ Codes:

PR-21393

Data di ultima modifica: 30/07/2020

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Marca/ Brand name:

Transflux CT 120

Modello/ Model:

Transflux CT 120 – CT/MRI Contrast connection line

Codici/ Codes:

PR-20202

Marca/ Brand name:

Transflux CT 150

Modello/ Model:

Transflux CT 150 – CT/MRI Contrast connection line

Codici/ Codes:

PR-21410

Marca/ Brand name:

Transflux CT 250

Modello/ Model:

Transflux CT 250 – CT/MRI Contrast connection line

Codici/ Codes:

PR-20203

Marca/ Brand name:

Transflux CT 45 – type GHB

Modello/ Model:

Transflux CT 45 – CT/MRI Contrast connection line – Type GHB

Codici/ Codes:

PR-21450

Marca/ Brand name:

Transflux CT 100 – type GHB

Modello/ Model:

Transflux CT 100 – CT/MRI Contrast connection line – Type GHB

Codici/ Codes:

PR-21414

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Marca/ Brand name:

Transflux CT 20 – type CF

Modello/ Model:

Transflux CT 20 – Type CF – CT/MRI Contrast connection line with mobile luer lock

Codici/ Codes:

PR-21417

Marca/ Brand name:

Transflux CT 45 – type CF

Modello/ Model:

Transflux CT 45 – Type CF – CT/MRI Contrast connection line with mobile luer lock

Codici/ Codes:

PR-21420

Marca/ Brand name:

Transflux CT 100 – type CF

Modello/ Model:

Transflux CT 100 – Type CF – CT/MRI Contrast connection line with mobile luer lock

Codici/ Codes:

PR-21418

Marca/ Brand name:

Transflux CT 150 – type CF

Modello/ Model:

Transflux CT 150 – Type CF – CT/MRI Contrast connection line with mobile luer lock

Codici/ Codes:

PR-21419

Marca/ Brand name:

Transflux MRI 150

Modello/ Model:

Transflux MRI 150 – MRI Contrast connection line

Codici/ Codes:

PR-20206



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Marca/ Brand name:

Transflux CT 160 - spiral

Modello/ Model

Transflux CT 160 – Spiral – CT/MRI contrast connection line in Spiral

Codici/ Codes:

PR-30100

Marca/ Brand name:

Transflux CT 200 - spiral

Modello/ Model

Transflux CT 200 – Spiral – CT/MRI contrast connection line in Spiral

Codici/ Codes:

PR-30200

Marca/ Brand name:

Transflux MRI 150 - spiral

Modello/ Model

Transflux MRI 150 – Spiral – MRI straight contrast connection line in Spiral

Codici/ Codes:

PR-30300

Modello/ Model

Administration contrast media system

Administration contrast media system in Y

Administration contrast media system in T

Injection and administration contrast media system

Clister bag

Clister bag with canula

Transvase system in J

Cannula for clister bag

Extensive line with check valve – 0,10m

Extensive line with check valve – 0,20m

Extensive line with check valve – 0,30m

Extensive line with check valve – 0,50m

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Extensive line with check valve – 0,60m
Extensive line with check valve – 1,00m
Extensive line with check valve – 1,20m
Extensive line with check valve – 1,50m
Extensive line with check valve – 2,00m
Extensive line without check valve – 0,10m
Extensive line without check valve – 0,50m
Extensive line without check valve – 1,20m
Extensive line without check valve – 1,50m
Extensive line without check valve – 1,60m
Extensive spiral line with 1 check valve – 1,50m
Extensive spiral line with 1 check valve – 2,00m
Extensive spiral line with 1 check valve – 2,50m
Extensive spiral line with 2 check valve – 1,50m
Extensive spiral line with 2 check valve – 2,50m
Extensive line with double check valve – VARD – 0,20m
Extensive line with double check valve – VARD – 0,30m
Extensive line with double check valve – VARD – 0,60m
Extensive line with double check valve – VARD – 1,20m
Extensive line with double check valve – VARD – 1,50m
Extensive line with double check valve – VARD – 2,50m

Codici/ Codes:

4001010, 4000102, 4001016, 4001111, 4001111C, 4000103-B, 4000104, 4001013, 3LSACLOE,
3LSACLOCE, 4001022, 99209, 330VA15, 330VA08, 330VA20, 330VA07, 330VA16, 330VA10,
330VA13, 330VA22, 330VA11, 330VA19, 330VA18, 330VA12, 330VA21, 3301VY12, 330VA17,
330VA14, 3300019, 3300008, 330SVA12, 330ESV14, 330SV14, 330SVA21, 330ESV21,
330SVY12, 330EY16, 330E1VY12, 330EVA12, 330E1VY13, 330E1VY14, 330E2VY12,
330E2VY13, 330VV08, 330VV12, 3304VY30, 330VV10, 330VV11, 330VV13, 3302VY12,
330VV14, 3302VY13,

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Tipologia/ Typology: Aspiration Systems

Modello/ Model:

Extensive line for aspiration – 2,00m

Extensive line for aspiration – 3,00m

Extensive line for aspiration – 4,00m

Vacudrain 500c.c.

Vacudrain 400c.c.

Vacudrain 200c.c.

Codici/ Codes:

4001237, 4001239, 4001115, 4001236, 4001115V, 0366TSIL, 0466TSIL, 4001021, 11825, 11824

Tipologia/ Typology: High Pressure lines and accessories

Modello/ Model:

High pressure line with male/female connector and valve – 0,50m

High pressure line with male/female connector and valve – 1,00m

High pressure line with male/female connector and valve – 1,20m

High pressure line with male/female connector and valve – 1,50m

High pressure line with male/female connector and valve – 2,00m

High pressure line with male/female connector and valve – 2,20m

High pressure line with male/male connector and valve – 0,50m

High pressure line with male/male connector and valve – 0,75m

High pressure line with male/male connector and valve – 1,00m

High pressure line with male/male connector and valve – 1,20m

High pressure line with male/male connector and valve – 1,40m

Data di ultima modifica: 30/07/2020
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High pressure line with male/male connector and valve – 1,50m
High pressure line with male/male connector and valve – 2,00m
High pressure line with male/female connector – 0,15m
High pressure line with male/female connector – 0,25m
High pressure line with male/female connector – 0,30m
High pressure line with male/female connector – 0,50m
High pressure line with male/female connector – 0,60m
High pressure line with male/female connector – 0,70m
High pressure line with male/female connector – 0,75m
High pressure line with male/female connector – 0,90m
High pressure line with male/female connector – 1,00m
High pressure line with male/female connector – 1,20m
High pressure line with male/female connector – 1,40m
High pressure line with male/female connector – 1,50m
High pressure line with male/female connector – 2,00m
High pressure line with male/male connector – 0,25m
High pressure line with male/male connector – 0,50m
High pressure line with male/male connector – 0,75m
High pressure line with male/male connector – 1,00m
High pressure line with male/male connector – 1,20m
High pressure line with male/male connector – 1,50m
High pressure line with male/male connector – 1,80m
High pressure line with male/male connector – 2,00m
High pressure line with female/male rotative connector – 0,30m
High pressure line with female/male rotative connector – 0,50m
High pressure line with female/male rotative connector – 0,75m
High pressure line with female/male rotative connector – 1,00m
High pressure line with female/male rotative connector – 1,20m
High pressure line with female/male rotative connector – 1,40m
High pressure line with female/male rotative connector – 1,50m

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High pressure line with female/male rotative connector – 1,80m
High pressure line with female/male rotative connector – 2,00m
High pressure line with female/male rotative connector – 2,50m
High pressure line with male/male rotative connector – 0,50m
High pressure line with male/male rotative connector – 0,75m
High pressure line with male/male rotative connector – 1,00m
High pressure line with male/male rotative connector – 1,20m
High pressure line with male/male rotative connector – 1,40m
High pressure line with male/male rotative connector – 1,50m
High pressure line with male/male rotative connector – 1,80m
High pressure line with male/male rotative connector – 2,00m
High pressure line with male/male connector and stopcock – 1,50m
High pressure line with male/female connector and stopcock – 1,50m
High pressure line with male/male connector, stopcock and protective mango – 1,50m
Check valve
High pressure ½ ways stopcock
High pressure 3 ways stopcock
Agger with 2 stopcocks - Right
Agger with 2 stopcocks - Left
Agger with 3 stopcocks - Right
Agger with 3 stopcocks - Left

Codici/ Codes:

4001220, 4001220R, 4011121, 4011121R, 4001128, 4001128R, 4011128, 4011128R, 4001132, 4001132R, 4001141, 4011145, 4011145R, 4011137, 4011137R, 4011144, 4011144R, 4011138, 4011138R, 4011139, 4011142, 4011142R, 4011143, 4011143R, 4001139, 4001135, 4001121, 4001136, 4001136R, 4001133, 4011125, 4001122, 4001122R, 4001134, 4001131, 4001131R, 4001123, 4001123R, 4001140, 4001118, 4001118R, 4001142R, 4001108, 4001108R, 4001137, 4001106R, 4001107, 4001107R, 4001105, 4001105R, 4001125, 4001125R, 4011118, 4011118R, 4011141, 4001145, 4001145R, 4001221, 4001143, 4001232B, 4001227, 4001231B, 4001218, 4001230B, 4001223, 4001228B, 4001240, 4001229, 4001229B, 4001232, 4011124, 4001242B, 4011140, 4001217, 4001217R, 4011224, 4011224R, 4001222, 4001222R, 4001216, 4001216R, 4001224, 4001235, 4001235B, 4001244, 4001244B, 4001226, 4001226R, 4001118MMT,

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4001118MFT, 4001118MMTS, 4001118MMTSPU, 4001112, 3306013, 3306016, 3306017R,
3306017L, 3306019R, 3306018R, 3306018L

Tipologia/ Typology: Perfusion systems and accessories

Marca/ Brand name:

P20Y

Modello/ Model:

Perfusion system with aerator and Y connector

Codici/ Codes:

1100007

Marca/ Brand name:

P20Y – VAR

Modello/ Model:

Perfusion system with aerator and Y connector

Codici/ Codes:

1100043

Marca/ Brand name:

P20Y – 2,00m

Modello/ Model:

Perfusion system with aerator and Y connector

Codici/ Codes:

1100014

Marca/ Brand name:

P20Y – B

Modello/ Model:

Perfusion system with aerator and Y connector

Codici/ Codes:

1100015

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Marca/ Brand name:

P18F

Modello/ Model:

Perfusion system with aerator and 15 micron filter

Codici/ Codes:

1100005

Marca/ Brand name:

P18F – 1,80M

Modello/ Model:

Perfusion system with aerator and 15 micron filter

Codici/ Codes:

1100036

Marca/ Brand name:

P18F without flashback

Modello/ Model:

Perfusion system with aerator and 15 micron filter

Codici/ Codes:

1100042

Marca/ Brand name:

P18

Modello/ Model:

Perfusion system with aerator

Codici/ Codes:

1100004

Marca/ Brand name:

P18Y

Modello/ Model:

Perfusion system with aerator, obturator and Y connector

Codici/ Codes:

1100006

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Marca/ Brand name:

P18FRF

Modello/ Model:

Perfusion system with flow regulator

Codici/ Codes:

1100008

Marca/ Brand name:

P12F

Modello/ Model:

Administration solution system for dialyses

Codici/ Codes:

1100001

Marca/ Brand name:

P12

Modello/ Model:

Administration solution system for dialyses

Codici/ Codes:

1100001SF

Marca/ Brand name:

P12F with filter and flashback

Modello/ Model:

Administration solution system for dialyses

Codici/ Codes:

1100035

Marca/ Brand name:

P60

Modello/ Model:

Microdrop solution administration system

Codici/ Codes:

1100013

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Last revision date:



Marca/ Brand name:

P60RF

Modello/ Model:

Microdrop solution administration system

Codici/ Codes:

1100024

Marca/ Brand name:

P120

Modello/ Model:

Microdrop solution administration system with graduated chamber 120 mL

Codici/ Codes:

1100114

Marca/ Brand name:

BHL-IVPC

Modello/ Model:

BHL-IV Peripheral Connector with three valves

Codici/ Codes:

BHL-IVPC-TV-20

Marca/ Brand name:

Monitoring line

Modello/ Model:

Arterial extensive line with male/female connector – 0,15m

Arterial extensive line with male/female connector – 0,25m

Arterial extensive line with male/female connector – 0,30m

Arterial extensive line with male/female connector – 0,50m

Arterial extensive line with male/female connector – 1,00m

Arterial extensive line with male/female connector – 1,50m

Arterial extensive line with male/female connector – 2,00m

Arterial extensive line with male/male connector – 0,05m

Codici/ Codes:

3302002R, 3302000R, 3302003, 3302014, 3302009R, 3302007R, 3302006R, 3303008R

Data di ultima modifica: **30/07/2020**

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Marca/ Brand name:

Venous line

Modello/ Model:

Arterial extensive line with male/female connector – 0,50m

Arterial extensive line with male/female connector – 1,00m

Arterial extensive line with male/female connector – 1,50m

Codici/ Codes:

3402004R, 3402009R, 3402008R

Modello/ Model:

Filling systems of nutrition bags

Transvase system

Central venous pressure measuring system

Polyvalent extensive line with male/female connector – 0,10m

Polyvalent extensive line with male/female connector – 0,15m

Polyvalent extensive line with male/female connector – 0,20m

Polyvalent extensive line with male/female connector – 0,25m

Polyvalent extensive line with male/female connector – 0,30m

Polyvalent extensive line with male/female connector – 0,50m

Polyvalent extensive line with male/female connector – 0,75m

Polyvalent extensive line with male/female connector – 1,00m

Polyvalent extensive line with male/female connector – 1,20m

Polyvalent extensive line with male/female connector – 1,50m

Polyvalent extensive line with male/female connector – 2,00m

Polyvalent extensive line with male/male connector – 0,25m

Polyvalent extensive line with male/male connector – 1,00m

Polyvalent extensive line with male/male connector – 2,00m

Polyvalent extensive line with rotative male connector 2,00m

Pediatric extensive line with male/female connector – 0,10m

Pediatric extensive line with male/female connector – 0,25m

Pediatric extensive line with male/female connector – 0,30m

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Mod. QMT_BSP_022 004 Rev.01

Pediatric extensive line with male/female connector – 0,50m
Pediatric extensive line with male/female connector – 0,75m
Pediatric extensive line with male/female connector – 1,00m
Pediatric extensive line with male/female connector – 1,50m
Pediatric extensive line with male/male connector – 1,00m
Arterial extensive line with male/female connector – 0,15m
Arterial extensive line with male/female connector – 0,20m
Arterial extensive line with male/female connector – 0,50m
Arterial extensive line with male/female connector – 0,60m
Arterial extensive line with male/female connector – 0,80m
Arterial extensive line with male/female connector – 1,00m
Arterial extensive line with male/female connector – 1,20m
Arterial extensive line with male/female connector – 1,25m
Arterial extensive line with male/female connector – 1,50m
Arterial extensive line with male/female connector – 1,80m
Arterial extensive line with male/female connector – 2,00m
Arterial extensive line with male/female connector – 2,50m
Arterial extensive line with male/male connector – 0,05m
Arterial extensive line with male/male connector – 1,00m
Arterial extensive line with male/male connector – 2,00m
Polyvalent extensive line with $\frac{3}{4}$ way stopcock – 0,05m
Polyvalent extensive line with $\frac{3}{4}$ way stopcock – 0,10m
Polyvalent extensive line with $\frac{3}{4}$ way stopcock – 0,15m
Polyvalent extensive line with $\frac{3}{4}$ way stopcock – 0,25m
Polyvalent extensive line with $\frac{3}{4}$ way stopcock – 0,30m
Polyvalent extensive line with $\frac{3}{4}$ way stopcock – 0,50m
Polyvalent extensive line with $\frac{3}{4}$ way stopcock – 0,75m
Polyvalent extensive line with $\frac{3}{4}$ way stopcock – 0,80m
Polyvalent extensive line with $\frac{3}{4}$ way stopcock – 1,00m
 $\frac{3}{4}$ way stopcock

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Codici/ Codes:

4001002, 4001104, 4001110, 3300002, 3300003, 3300004, 3300005, 3300006, 3300007,
3300009, 3300010, 3300011, 3300012, 3300013, 3301002, 3301004, 3300113, 3302010,
3305000, 3305002, 3305003, 3305001, 3305004, 3305005, 3305006, 3305007, 3302002,
3302001, 3302004, 3302017, 3302011, 3302009, 3302005, 3302012, 3302007, 3302013,
3302006, 3302019, 3303008, , 3303004R, 3303006, 3306001, 3306005, 3306006, 3306020,
3306010, 3306009, 3306008, 3306011, 3306023, 3306014

Tipologia/ Typology: Irrigation systems and accessories

Modello/ Model:

System for cystoscopy and vesical irrigation – LL

System for cystoscopy and vesical irrigation without chamber

System for cystoscopy and vesical irrigation with silicone terminal

System in Y for arthroscopy

Irrigation system for laparoscopy

Double channel spike

One channel spike

Codici/ Codes:

4001001, 4001011, 4001101, 4001014, 4001114, 9909750300, 4001009, 8503330301

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