

Oświadczenie Producenta

W związku z Rozporządzeniem (UE) 2023/607 zmieniającym Rozporządzenie (UE) 2017/745 w odniesieniu do przepisów przejściowych dotyczących niektórych wyrobów medycznych, zwłaszcza w odniesieniu do:

- Ważności certyfikatów wydanych na podstawie Dyrektywy Rady 93/42/EWG w sprawie wyrobów medycznych (MDD)
- Zgodności wyrobów i BHL-Medical, jako ich producenta, z warunkami kontynuowania wprowadzania na rynek i oddawania do użytku

Nazwa producenta	BHL-Medical, Industria de Produtos Hospitalares, Lda
Adres producenta oraz dane kontaktowe	Estrada da Avesada n.º 390 2665-402 Santo Estevão das Galés, Portugal Telefon: +351 219821694 Email: geral@bhl-medical.com
Numer Jednolitego Numeru Rejestracyjnego (SRN)	PT-MF-000002811

Nazwa jednostki notyfikowanej	TÜV Rheinland Italia S.r.l.
Numer jednostki notyfikowanej	1936
Numer certyfikatu zgodności z dyrektywą, do której odnosi się to potwierdzenie	DD 60133728 (MDD Annex V)
Oryginalna data ważności, jak wskazano na certyfikacie zgodności z dyrektywą przed przedłużeniem ważności	10 grudnia 2023
Data zakończenia przedłużonej ważności/okresu przejściowego	31 grudnia 2028

BHL-Medical, jako producent, oświadcza pod swoją wyłączną odpowiedzialnością, że wymienione urządzenia w załączonym harmonogramie spełniają warunki określone w artyku 120.3c rozporządzenia MDR dotyczącego kontynuacji wprowadzania na rynek i oddawania do użytku, mianowicie spełniając poniższe warunki:

- Certyfikaty dyrektyw, jak wymienione w załączonej tabeli:
 - Certyfikat dyrektywy obejmujący wymienione urządzenia został wydany po 25 maja 2017 roku, był ważny 26 maja 2021 roku i nie został wycofany po tej dacie.

Przed oryginalną datą ważności, jak wskazano na certyfikacie dyrektywy, BHL-Medical i Jednostka Notyfikowana podpisały pisemną umowę zgodnie z § 4.3, drugim akapitem Załącznika VII do rozporządzenia w sprawie oceny zgodności w odniesieniu do urządzeń objętych wygasłym certyfikatem.
- System Zarządzania Jakością (QMS)

Jednostka notyfikowana wydała załączony certyfikat dla Systemu Zarządzania Jakością zgodnego z MDR.
- Urządzenia, jak wymienione w załączonej tabeli:
 - Urządzenia nadal spełniają wymagania MDD.
 - Nie wystąpiły istotne zmiany w projekcie i przeznaczeniu.
 - Urządzenia nie stwarzają nieakceptowalnego ryzyka dla zdrowia lub bezpieczeństwa pacjentów, użytkowników lub innych osób ani innych aspektów ochrony zdrowia publicznego.

Podpisane w imieniu producenta:

BHL-Medical, Industria de Produtos Hospitalares, Lda
Santo Estevão das Galés, 27 listopada 2023

Celia Ludovino

Odpowiedzialna za regulacje i zgodność

Manufacturer Declaration

in relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices and, in particular with respect to:

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD)
- the compliance of the devices and BHL-Medical, as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	BHL-Medical , Indústria de Produtos Hospitalares, Lda
Manufacturer address and contact details	Estrada da Aversada n.º 390 2665-402 – Santo Estêvão das Galés, Portugal Phone: +351 219821694 e-mail: geral@bhl-medical.com
Single Registration Number (SRN)	PT-MF-000002811

Notified body name	TÜV Rheinland Italia S.r.l
Notified body number	1936
Directive Certificate number to which this confirmation is made	DD 60133728 (MDD Annex V)
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	10 December 2023
End date of extended validity/transition period	31 December 2028

BHL-Medical, as the manufacturer declares under its sole responsibility:

the listed devices in the attached schedule are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

➤ **Directive Certificates as listed in the attached table:**

- Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.

Before the original date of expiry as indicated on the Directive Certificate, BHL-Medical and the Notified Body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to the Regulation for the conformity assessment in respect of the devices covered by the expired certificate.

➤ **Quality Management System (QMS)**

A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Devices as listed in the attached table:**

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed on behalf of the manufacturer:

BHL-Medical, Indústria de Produtos Hospitalares, Lda
Santo Estêvão das Galés, 27th November 2023



Célia Ludovino

Responsible for Regulatory and Compliance

The above Manufacturer Declaration is valid for the following devices identified on the table:

Device name	Reference	Class	UDI	BASIC UDI
Administration contrast media system	4001010	Ia	05600988813255	056009888TF001KU
Administration contrast media system in Y	4001016	Ia	05600988817147	056009888TF001KU
Administration contrast media system in Y	400104	Ia	05600988817437	056009888TF001KU
Administration contrast media system in Y	400102	Ia	05600988815709	056009888TF001KU
Administration contrast media system in T	400111	Ia	05600988814320	056009888TF001KU
Administration contrast media system in T	400111C	Ia	05600988817642	056009888TF001KU
Administration contrast media system in T	400103-B	Ia	05600988828969	056009888TF001KU
Transset Mono syringe Contrast filling & injection set	PR-20197	Ia	05600988820611	056009888TF001KU
Transset duo syringe Contrast filling & injection set	PR-20198	Ia	05600988820604	056009888TF001KU
Transset duo syringe Contrast filling & injection set in spiral	PR-30510	Ia	05600988827054	056009888TF001KU
Transset duo syringe Contrast filling & injection set for MRI	PR-20194	Ia	05600988827641	056009888TF001KU
Transset duo syringe Contrast filling & injection set for MRI in spiral	PR-30511	Ia	05600988827061	056009888TF001KU
Transvase system in J	4001022	Ia	05600988801191	056009888TF001KU
2-way spike with female connection	4001009	Ia	05600988813231	056009888TF003KY
2-way spike	9909750300	Ia	05600988806462	056009888TF003KY
1-way spike	8503330301	Ia	05600988800378	056009888TF003KY
Extensive line with check valve – 0,20m	330VA08	Ia	05600988813903	056009888TF001KU
Extensive line with check valve – 0,30m	330VA16	Ia	05600988814009	056009888TF001KU
Extensive line with check valve – 0,50m	330VA13	Ia	05600988816751	056009888TF001KU
Extensive line with check valve – 1,20m	330VA18	Ia	05600988814023	056009888TF001KU
Extensive line with check valve – 1,50m	330VA21	Ia	05600988816638	056009888TF001KU
Extensive line with check valve – 2,00m	330VA17	Ia	05600988816768	056009888TF001KU
Extensive line with check valve – 1,50m	3301VY12	Ia	05600988817406	056009888TF001KU
Extensive line without check valve – 0,10m	3300019	Ia	05600988818441	056009888TF001KU
Extensive line without check valve – 0,50m	3300008	Ia	05600988816164	056009888TF001KU
Extensive line without check valve – 1,20m	330SVA12	Ia	05600988820185	056009888TF001KU
Extensive line without check valve – 1,50m	330SV14	Ia	05600988819165	056009888TF001KU
Extensive line without check valve – 1,50m	330ESV14	Ia	05600988819172	056009888TF001KU
Extensive line without check valve – 1,50m	330SVA21	Ia	05600988817543	056009888TF001KU
Extensive line without check valve – 1,50m	330ESV21	Ia	05600988819189	056009888TF001KU
Extensive line without check valve – 1,50m	330SVY12	Ia	05600988817420	056009888TF001KU
Extensive line without check valve – 1,60m	330EY16	Ia	05600988816737	056009888TF001KU
Extensive spiral line with 1 check valve – 1,50m	330E1VY12	Ia	05600988816904	056009888TF001KU
Extensive spiral line with 1 check valve – 2,00m	330E1VY13	Ia	05600988817000	056009888TF001KU
Extensive spiral line with 1 check valve – 2,50m	330E1VY14	Ia	05600988826385	056009888TF001KU
Extensive spiral line with 1 check valve – 1,50m	330EVA12	Ia	05600988824237	056009888TF001KU
Extensive spiral line with 1 check valve – 1,50m	BHL-SVC-150	Ia	05600988826347	056009888TF001KU
Extensive spiral line with 1 check valve – 2,00m	BHL-SVC-200	Ia	05600988826354	056009888TF001KU

Extensive line with check valve and LLM - 0,20m	BHL-SVM-20	Ila	05600988826200	0560098881F001KU
Extensive line with check valve and LLM - 0,30m	BHL-SVM-30	Ila	05600988826217	0560098881F001KU
Extensive line with check valve and LLM - 0,60m	BHL-SVM-60	Ila	05600988826224	0560098881F001KU
Extensive line with check valve and LLM - 1,20m	BHL-SVM-120	Ila	05600988826231	0560098881F001KU
Extensive line with check valve and LLM - 1,50m	BHL-SVM-150	Ila	05600988826248	0560098881F001KU
Extensive line with check valve and LLM - 2,00m	BHL-SVM-200	Ila	05600988826255	0560098881F001KU
Extensive line with check valve and LLM - 2,50m	BHL-SVM-250	Ila	05600988826262	0560098881F001KU
Extensive spiral line with 2 check valve- 1,50m	330E2VY12	Ila	05600988816911	0560098881F001KU
Extensive spiral line with 2 check valve- 2,50m	330E2VY13	Ila	05600988819530	0560098881F001KU
Extensive spiral line with 2 check valve - 1,50m	BHL-DVC-150	Ila	05600988826361	0560098881F001KU
Extensive spiral line with 2 check valve- 2,00m	BHL-DVC-200	Ila	05600988826378	0560098881F001KU
Extensive line with double check valve for bilateral phlebography - 0,80m	330ZVY14	Ila	05600988820345	0560098881F001KU
Extensive line with double check valve - VARD - 1,50m	330ZVY12	Ila	05600988817505	0560098881F001KU
Extensive line with double check valve - VARD - 2,50m	330ZVY13	Ila	05600988824060	0560098881F001KU
Extensive line with double check valve and LLM - 0,20m	BHL-DVM-20	Ila	05600988826279	0560098881F001KU
Extensive line with double check valve and LLM - 0,30m	BHL-DVM-30	Ila	05600988826286	0560098881F001KU
Extensive line with double check valve and LLM - 0,60m	BHL-DVM-60	Ila	05600988826293	0560098881F001KU
Extensive line with double check valve and LLM - 1,20m	BHL-DVM-120	Ila	05600988826309	0560098881F001KU
Extensive line with double check valve and LLM - 1,50m	BHL-DVM-150	Ila	05600988826316	0560098881F001KU
Extensive line with double check valve and LLM - 2,00m	BHL-DVM-200	Ila	05600988826323	0560098881F001KU
Extensive line with double check valve and LLM - 2,50m	BHL-DVM-250	Ila	05600988826330	0560098881F001KU
Transflux CT 20 - CT/MRI Contrast connection line	PR-20199	Ila	05600988820536	0560098881F001KU
Transflux CT 45 - CT/MRI Contrast connection line	PR-21379	Ila	05600988820543	0560098881F001KU
Transflux CT 60 - CT/MRI Contrast connection line	PR-20201	Ila	05600988820550	0560098881F001KU
Transflux CT 100 - CT/MRI Contrast connection line	PR-21393	Ila	05600988820567	0560098881F001KU
Transflux CT 120 - CT/MRI Contrast connection line	PR-20202	Ila	05600988820574	0560098881F001KU
Transflux CT 150 - CT/MRI Contrast connection line	PR-21410	Ila	05600988820581	0560098881F001KU
Transflux CT 250 - CT/MRI Contrast connection line	PR-20203	Ila	05600988820598	0560098881F001KU
Transflux CT 45 - CT/MRI Contrast connection line - Type GHB	PR-21450	Ila	05600988820529	0560098881F001KU
Transflux CT 100 - CT/MRI Contrast connection line - Type GHB	PR-21414	Ila	05600988820499	0560098881F001KU
Transflux CT 20 - Type CF - CT/MRI Contrast connection line with mobile luer lock	PR-21417	Ila	05600988820499	0560098881F001KU
Transflux CT 45 - Type CF - CT/MRI Contrast connection line with mobile luer lock	PR-21420	Ila	05600988826170	0560098881F001KU
Transflux CT 100 - Type CF - CT/MRI Contrast connection line with mobile luer lock	PR-21418	Ila	05600988826187	0560098881F001KU
Transflux CT 150 - Type CF - CT/MRI Contrast connection line with mobile luer lock	PR-21419	Ila	05600988826194	0560098881F001KU
Transflux MRI 150 - MRI Contrast connection line	PR-20206	Ila	05600988820505	0560098881F001KU
Transflux CT 160 - Spiral - CT/MRI contrast connection line in Spiral	PR-30100	Ila	05600988827580	0560098881F001KU
Transflux CT 200 - Spiral - CT/MRI contrast connection line in Spiral	PR-30200	Ila	05600988825920	0560098881F001KU
Transflux MRI 150 - Spiral - MRI straight contrast connection line in Spiral	PR-30300	Ila	05600988827597	0560098881F001KU
High pressure line with male/female connector and valve - 0,50m	BHL-HFMFV-50	Ila	05600988829768	0560098881F002KW
High pressure line with male/female connector and valve - 1,00m	BHL-HFMFV-100	Ila	05600988829775	0560098881F002KW
High pressure line with male/female connector and valve - 1,20m	BHL-HFMFV-120	Ila	05600988829782	0560098881F002KW
High pressure line with male/female connector and valve - 1,50m	BHL-HFMFV-150	Ila	05600988829799	0560098881F002KW
High pressure line with male/female connector and valve - 2,00m	BHL-HFMFV-200	Ila	05600988829805	0560098881F002KW

High pressure line with male/female connector and valve – 0,50m	BHL-HFMFVB2-50	Ila	05600988829812	056009888TF002KW
High pressure line with male/female connector and valve – 1,00m	BHL-HFMFVB2-100	Ila	05600988829829	056009888TF002KW
High pressure line with male/female connector and valve – 1,20m	BHL-HFMFVB2-120	Ila	05600988829836	056009888TF002KW
High pressure line with male/female connector and valve – 1,50m	BHL-HFMFVB2-150	Ila	05600988829843	056009888TF002KW
High pressure line with male/female connector and valve – 2,00m	BHL-HFMFVB2-200	Ila	05600988829850	056009888TF002KW
High pressure line with male/male connector and valve – 0,50m	BHL-HFMMV-50	Ila	05600988829867	056009888TF002KW
High pressure line with male/male connector and valve – 0,75m	BHL-HFMMV-75	Ila	05600988829874	056009888TF002KW
High pressure line with male/male connector and valve – 1,00m	BHL-HFMMV-100	Ila	05600988829881	056009888TF002KW
High pressure line with male/male connector and valve – 1,20m	BHL-HFMMV-120	Ila	05600988829898	056009888TF002KW
High pressure line with male/male connector and valve – 1,50m	BHL-HFMMV-150	Ila	05600988829904	056009888TF002KW
High pressure line with male/male connector and valve – 2,00m	BHL-HFMMV-200	Ila	05600988829911	056009888TF002KW
High pressure line with male/male connector and valve – 0,50m	BHL-HFMMVB2-50	Ila	05600988829928	056009888TF002KW
High pressure line with male/male connector and valve – 0,75m	BHL-HFMMVB2-75	Ila	05600988829935	056009888TF002KW
High pressure line with male/male connector and valve – 1,00m	BHL-HFMMVB2-100	Ila	05600988829942	056009888TF002KW
High pressure line with male/male connector and valve – 1,20m	BHL-HFMMVB2-120	Ila	05600988829959	056009888TF002KW
High pressure line with male/male connector and valve – 1,50m	BHL-HFMMVB2-150	Ila	05600988829966	056009888TF002KW
High pressure line with male/male connector and valve – 2,00m	BHL-HFMMVB2-200	Ila	05600988829973	056009888TF002KW
High pressure line with male/female connector – 0,30m	BHL-HFMF-30	Ila	05600988829980	056009888TF002KW
High pressure line with male/female connector – 0,50m	BHL-HFMF-50	Ila	05600988829997	056009888TF002KW
High pressure line with male/female connector – 0,75m	BHL-HFMF-75	Ila	05600988830009	056009888TF002KW
High pressure line with male/female connector – 1,00m	BHL-HFMF-100	Ila	05600988830016	056009888TF002KW
High pressure line with male/female connector – 1,20m	BHL-HFMF-120	Ila	05600988830023	056009888TF002KW
High pressure line with male/female connector – 1,50m	BHL-HFMF-150	Ila	05600988830030	056009888TF002KW
High pressure line with male/female connector – 2,00m	BHL-HFMF-200	Ila	05600988830047	056009888TF002KW
High pressure line with male/female connector – 0,50m	BHL-HFMFB1-50	Ila	05600988830054	056009888TF002KW
High pressure line with male/female connector – 0,75m	BHL-HFMFB1-75	Ila	05600988830078	056009888TF002KW
High pressure line with male/female connector – 1,00m	BHL-HFMFB1-100	Ila	05600988830085	056009888TF002KW
High pressure line with male/female connector – 1,20m	BHL-HFMFB1-120	Ila	05600988830092	056009888TF002KW
High pressure line with male/female connector – 1,50m	BHL-HFMFB1-150	Ila	05600988830108	056009888TF002KW
High pressure line with male/female connector – 2,00m	BHL-HFMFB1-200	Ila	05600988830115	056009888TF002KW
High pressure line with male/female connector – 1,50m	BHL-HFMFB2-150	Ila	05600988830122	056009888TF002KW
High pressure line with male/male connector – 0,75m	BHL-HFMM-75	Ila	05600988830139	056009888TF002KW
High pressure line with male/male connector – 1,00m	BHL-HFMM-100	Ila	05600988830146	056009888TF002KW
High pressure line with male/male connector – 1,20m	BHL-HFMM-120	Ila	05600988830153	056009888TF002KW
High pressure line with male/male connector – 1,50m	BHL-HFMM-150	Ila	05600988830160	056009888TF002KW
High pressure line with male/male connector – 1,80m	BHL-HFMM-180	Ila	05600988830177	056009888TF002KW
High pressure line with male/male connector – 2,00m	BHL-HFMM-200	Ila	05600988830184	056009888TF002KW
High pressure line with male/male connector – 0,50m	BHL-HFMMB2-50	Ila	05600988830191	056009888TF002KW
High pressure line with male/male connector – 0,75m	BHL-HFMMB2-75	Ila	05600988830207	056009888TF002KW
High pressure line with male/male connector – 1,00m	BHL-HFMMB2-100	Ila	05600988830214	056009888TF002KW
High pressure line with male/male connector – 1,20m	BHL-HFMMB2-120	Ila	05600988830221	056009888TF002KW
High pressure line with male/male connector – 1,50m	BHL-HFMMB2-150	Ila	05600988830238	056009888TF002KW
High pressure line with male/male connector – 2,00m	BHL-HFMMB2-200	Ila	05600988830245	056009888TF002KW

High pressure line with female/male relative connector – 0,30m	BHL-HFFMR-30	Ila	05600988830252	0560098881F002kV
High pressure line with female/male relative connector – 0,50m	BHL-HFFMR-50	Ila	05600988830269	0560098881F002kV
High pressure line with female/male relative connector – 0,75m	BHL-HFFMR-75	Ila	05600988830276	0560098881F002kV
High pressure line with female/male relative connector – 1,00m	BHL-HFFMR-100	Ila	05600988830283	0560098881F002kV
High pressure line with female/male relative connector – 1,20m	BHL-HFFMR-120	Ila	05600988830290	0560098881F002kV
High pressure line with female/male relative connector – 1,50m	BHL-HFFMR-150	Ila	05600988830306	0560098881F002kV
High pressure line with female/male relative connector – 1,80m	BHL-HFFMR-180	Ila	05600988830313	0560098881F002kV
High pressure line with female/male relative connector – 2,00m	BHL-HFFMR-200	Ila	05600988830320	0560098881F002kV
High pressure line with female/male relative connector – 2,50m	BHL-HFFMR-250	Ila	05600988830337	0560098881F002kV
High pressure line with female/male relative connector – 3,00m	BHL-HFFMR-300	Ila	05600988830344	0560098881F002kV
High pressure line with female/male relative connector – 0,50m	BHL-HFFMRB1-50	Ila	05600988830351	0560098881F002kV
High pressure line with female/male relative connector – 0,75m	BHL-HFFMRB1-75	Ila	05600988830368	0560098881F002kV
High pressure line with female/male relative connector – 1,00m	BHL-HFFMRB1-100	Ila	05600988830375	0560098881F002kV
High pressure line with female/male relative connector – 1,20m	BHL-HFFMRB1-120	Ila	05600988830382	0560098881F002kV
High pressure line with female/male relative connector – 1,50m	BHL-HFFMRB1-150	Ila	05600988830399	0560098881F002kV
High pressure line with female/male relative connector – 2,00m	BHL-HFFMRB1-200	Ila	05600988830405	0560098881F002kV
High pressure line with female/male relative connector – 0,50m	BHL-HFFMR-50	Ila	05600988830412	0560098881F002kV
High pressure line with female/male relative connector – 0,75m	BHL-HFFMR-75	Ila	05600988830429	0560098881F002kV
High pressure line with female/male relative connector – 1,00m	BHL-HFFMR-100	Ila	05600988830436	0560098881F002kV
High pressure line with female/male relative connector – 1,20m	BHL-HFFMR-120	Ila	05600988830443	0560098881F002kV
High pressure line with female/male relative connector – 1,50m	BHL-HFFMR-150	Ila	05600988830450	0560098881F002kV
High pressure line with female/male relative connector – 1,80m	BHL-HFFMR-180	Ila	05600988830467	0560098881F002kV
High pressure line with female/male relative connector – 2,00m	BHL-HFFMR-200	Ila	05600988830474	0560098881F002kV
High pressure line with female/male relative connector – 0,50m	BHL-HFFMRB2-50	Ila	05600988830481	0560098881F002kV
High pressure line with female/male relative connector – 0,75m	BHL-HFFMRB2-75	Ila	05600988830498	0560098881F002kV
High pressure line with female/male relative connector – 1,00m	BHL-HFFMRB2-100	Ila	05600988830504	0560098881F002kV
High pressure line with female/male relative connector – 1,20m	BHL-HFFMRB2-120	Ila	05600988830511	0560098881F002kV
High pressure line with female/male relative connector – 1,50m	BHL-HFFMRB2-150	Ila	05600988830528	0560098881F002kV
High pressure line with female/male relative connector – 1,80m	BHL-HFFMRB2-180	Ila	05600988830535	0560098881F002kV
High pressure line with female/male relative connector – 2,00m	BHL-HFFMRB2-200	Ila	05600988830542	0560098881F002kV
High pressure line with male/female connector and stopcock – 1,50m	BHL-HFFMS-150	Ila	05600988830559	0560098881F002kV
High pressure line with male/female connector, stopcock and protective sleeve – 1,50m	BHL-HFFMSS-150	Ila	05600988830566	0560098881F002kV
High pressure line with male/male connector, stopcock and protective sleeve – 1,50m	BHL-HFFMSSSB-150	Ila	05600988830573	0560098881F002kV
High pressure ½ ways stopcock	3306013	Ila	05600988813538	0560098881F002kV
High pressure 3 ways stopcock	3306016	Ila	05600988813576	0560098881F002kV
2 stopcock manifold - Right -off	3306017R	Ila	05600988817680	0560098881F002kV
2 stopcock manifold - Left -off	3306017L	Ila	05600988817758	0560098881F002kV
3 stopcock manifold - Right - on	3306019R	Ila	05600988818601	0560098881F002kV
3 stopcock manifold - Right - off	3306018R	Ila	05600988817741	0560098881F002kV
3 stopcock manifold - Left - off	3306018L	Ila	05600988817673	0560098881F002kV
System for cystoscopy and vesical irrigation - LL	4001001	Is	05600988801719	0560098881F003kV
System for cystoscopy and vesical irrigation	4001011	Is	05600988802938	0560098881F003kV
System for cystoscopy and vesical irrigation with silicone terminal	4001101	Is	05600988802914	0560098881F003kV

System in Y for arthroscopy	4001014	Is	05600988813286	056009888TF003KY
Irrigation system for laparoscopy	4001114	Is	05600988813880	056009888TF003KY
Perfusion system with aerator	1100117A	Ila	05600988818328	056009888TF003KY
Perfusion system with aerator	1100117C	Ila	05600988819424	056009888TF003KY
Perfusion system with aerator	1100117D	Ila	05600988818571	056009888TF003KY
Transvase system	4001104	Is	05600988814412	056009888TF003KY
Polyvalent extensive line with rotative male connector 2,00m	3302010	Is	05600988813484	056009888TF003KY
Perfusion system with aerator and Y connector	1100007	Is	05600988800026	056009888TF005L4
Perfusion system with aerator and 15 micron filter	1100005	Is	05600988800040	056009888TF005L4
Perfusion system with aerator and 15 micron filter	1100042	Is	05600988820369	056009888TF005L4
Perfusion system with flow regulator	1100008	Is	05600988813453	056009888TF005L4
Microdrop solution administration system	1100013	Is	05600988800293	056009888TF005L4
Microdrop solution administration system	1100024	Is	05600988817734	056009888TF005L4
Microdrop solution administration system with graduated chamber 120 mL	1100114	Is	05600988800279	056009888TF005L4
BHL-IV Peripheral Connector with three valves	BHL-IVPC-TV-20	Is	05600988827856	056009888TF005L4
Polyvalent extensive line with male/female connector - 0,10m	3300002	Is	05600988813941	056009888TF005L4
Polyvalent extensive line with male/female connector - 0,30m	3300006	Is	05600988805311	056009888TF005L4
Polyvalent extensive line with male/female connector - 0,50m	3300007	Is	05600988801825	056009888TF005L4
Polyvalent extensive line with male/female connector - 1,00m	3300010	Is	05600988800316	056009888TF005L4
Polyvalent extensive line with male/female connector - 1,20m	3300011	Is	05600988816843	056009888TF005L4
Polyvalent extensive line with male/female connector - 1,50m	3300012	Is	05600988810964	056009888TF005L4
Polyvalent extensive line with male/female connector - 2,00m	3300013	Is	05600988813866	056009888TF005L4
Polyvalent extensive line with male/male connector - 0,25m	3301002	Is	05600988815273	056009888TF005L4
Polyvalent extensive line with male/male connector - 1,00m	3301004	Is	05600988813767	056009888TF005L4
Polyvalent extensive line with male/male connector - 2,00m	3301113	Is	05600988817802	056009888TF005L4
Paediatric extensive line with male/female connector - 0,30m	3305003	Is	05600988816959	056009888TF005L4
Paediatric extensive line with male/female connector - 0,50m	3305001	Is	05600988817482	056009888TF005L4
Paediatric extensive line with male/female connector - 1,00m	3305005	Is	05600988816942	056009888TF005L4
Paediatric extensive line with male/female connector - 1,50m	3305006	Is	05600988811589	056009888TF005L4
Paediatric extensive line with male/male connector - 1,00m	3305007	Is	05600988817192	056009888TF005L4
Arterial extensive line with male/female connector - 0,30m	3302003	Is	05600988805342	056009888TF005L4
Arterial extensive line with male/female connector - 1,00m	3302009	Is	05600988816119	056009888TF005L4
Arterial extensive line with male/female connector - 1,20m	3302005	Is	05600988813859	056009888TF005L4
Arterial extensive line with male/female connector - 1,50m	3302007	Is	05600988811572	056009888TF005L4
Arterial extensive line with male/female connector - 2,00m	3302006	Is	05600988807827	056009888TF005L4
Arterial extensive line with male/female connector - 2,50m	3302019	Is	05600988819691	056009888TF005L4
Arterial extensive line with male/female connector - 0,15m	3302002R	Is	05600988818946	056009888TF005L4
Arterial extensive line with male/female connector - 0,50m	3302014	Is	05600988817864	056009888TF005L4
Arterial extensive line with male/female connector - 1,00m	3302009R	Is	05600988818977	056009888TF005L4
Arterial extensive line with male/female connector - 1,50m	3302007R	Is	05600988818960	056009888TF005L4
Arterial extensive line with male/female connector - 2,00m	3302006R	Is	05600988818953	056009888TF005L4
Arterial extensive line with male/female connector - 0,50m	3402004R	Is	05600988818922	056009888TF005L4
Arterial extensive line with male/female connector - 1,00m	3402009R	Is	05600988818939	056009888TF005L4

Arterial extensive line with male/female connector - 1,50m	3402008R	Is	05600988820444	056009888TF005L4
Arterial extensive line with male/male connector - 2,00m	3303006	Is	05600988807834	056009888TF005L4
Arterial extensive line with male/male connector - 1,00m	3303004R	Is	05600988819004	056009888TF005L4
Polyvalent extensive line with ¾ way stopcock - 0,10m	3306005	Is	05600988803041	056009888TF005L4
Polyvalent extensive line with ¾ way stopcock - 0,30m	3306010	Is	05600988813873	056009888TF005L4
Polyvalent extensive line with ¾ way stopcock - 0,50m	3306009	Is	05600988813774	056009888TF005L4
Polyvalent extensive line with ¾ way stopcock - 0,75m	3306008	Is	05600988816898	056009888TF005L4
Polyvalent extensive line with ¾ way stopcock - 1,00m	3306023	Is	05600988818359	056009888TF005L4
¾ way stopcock	3306014	Is	05600988802952	056009888TF005L4
Check valve gravity	BHL-VFM-100	Is	05600988816850	056009888TF005L4
Extensive line for aspiration - 2,00m	4001237	Is	05600988817727	056009888TF004L2
Extensive line for aspiration - 3,00m	4001236	Is	05600988817598	056009888TF004L2
Extensive line for aspiration - 2,00m	4001115V	Is	05600988813897	056009888TF004L2
Extensive line for aspiration - 3,00m	4001239	Is	05600988818403	056009888TF004L2
Extensive line for aspiration - 2,00m	0366TSIL	Is	05600988818069	056009888TF004L2
Extensive line for aspiration - 3,00m	0466TSIL	Is	05600988819769	056009888TF004L2
Extensive line for aspiration - 4,00m	4001021	Is	05600988819813	056009888TF004L2
Vacudrain 500 c.c				

The following references included in the certificate above are not covered by this confirmation letter:

4001013, 330VA15, 330VA20, 330VA07, 330VA10, 330VA22, 330VA11, 330VA19, 330VA12, 330VA14, 330VV08, 330VV12, 3304VY30, 330VV10, 330VV11, 330VV13, 330VV14, 3LSACLOE, 99209, 3LSACLOCE, 4001141, 4011139, 4001139, 4001135, 4001133, 4011125, 4001134, 4001140, 4001137, 4001240, 4001224, 4001112, 1100043, 1100014, 1100015, 1100036, 1100004, 1100006, 1100001, 1100001SF, 1100035, 3302000R, 3303008R, 4001002, 4001110, 3300003, 3300004, 3300005, 3300009, 3305000, 3305002, 3305004, 3302002, 3302001, 3302004, 3302017, 3302011, 3302012, 3302013, 3303008, 3306001, 3306006, 3306020, 3306011.

For some products included in the certificate No. DD60133728 and covered by this declaration, BHL proposed a change of references for the transition to MDR. Correspondence between references are identified on the following table:

Device REF under MDD certificate	Device REF under MDR application
4001220	BHL-HFMFV-50
4001121	BHL-HFMFV-100
4001128	BHL-HFMFV-120
4011128	BHL-HFMFV-150
4001132	BHL-HFMFV-200
4001220R	BHL-HFMFVB2-50
4011121R	BHL-HFMFVB2-100
4001128R	BHL-HFMFVB2-120
4011128R	BHL-HFMFVB2-150
4001132R	BHL-HFMFVB2-200
4011145	BHL-HFMMV-50
4011137	BHL-HFMMV-75
4011144	BHL-HFMMV-100
4011138	BHL-HFMMV-120
4011142	BHL-HFMMV-150
4011143	BHL-HFMMV-200
4011145R	BHL-HFMMVB2-50
4011137R	BHL-HFMMVB2-75
4011144R	BHL-HFMMVB2-100
4011138R	BHL-HFMMVB2-120
4011142R	BHL-HFMMVB2-150
4011143R	BHL-HFMMVB2-200
4001217R	BHL-HFMMRB2-50
4011224R	BHL-HFMMRB2-75
4001222R	BHL-HFMMRB2-100
4001216R	BHL-HFMMRB2-120
4001235B	BHL-HFMMRB2-150
4001244B	BHL-HFMMRB2-180
4001226R	BHL-HFMMRB2-200

Device REF under MDD certificate	Device REF under MDR application
4001121	BHL-HFMF-30
4001136	BHL-HFMF-50
4001122	BHL-HFMF-75
4001131	BHL-HFMF-100
4001123	BHL-HFMF-120
4001118	BHL-HFMF-150
4001108	BHL-HFMF-200
4001136R	BHL-HFMFB1-50
4001122R	BHL-HFMFB1-75
4001142R	BHL-HFMFB1-150
4001108R	BHL-HFMFB1-200
4001131R	BHL-HFMFB2-100
4001123R	BHL-HFMFB2-120
4001118R	BHL-HFMFB2-150
4001107	BHL-HFMM-75
4001105	BHL-HFMM-100
4001125	BHL-HFMM-120
4011118	BHL-HFMM-150
4011141	BHL-HFMM-180
4001145	BHL-HFMM-200
4001106R	BHL-HFMMB2-50
4001107R	BHL-HFMMB2-75
4001118MMT	BHL-HFMMS-150
4001118MFT	BHL-HFMFS-150
4001118MMTS	BHL-HFMMSS-150
4001118MMTSPU	BHL-HFMMSSB2-150

Device REF under MDD certificate	Device REF under MDR application
4001105R	BHL-HFMMB2-100
4001125R	BHL-HFMMB2-120
4011118R	BHL-HFMMB2-150
4001145R	BHL-HFMMB2-200
4001221	BHL-HFFMR-30
4001143	BHL-HFFMR-50
4001227	BHL-HFFMR-75
4001218	BHL-HFFMR-100
4001223	BHL-HFFMR-120
4001229	BHL-HFFMR-150
4001232	BHL-HFFMR-180
4011124	BHL-HFFMR-200
4011140	BHL-HFFMR-250
4001232B	BHL-HFFMRB1-50
4001231B	BHL-HFFMRB1-75
4001230B	BHL-HFFMRB1-100
4001228B	BHL-HFFMRB1-120
4001229B	BHL-HFFMRB1-150
4001242B	BHL-HFFMRB1-200
4001217	BHL-HFFMMR-50
4011224	BHL-HFFMMR-75
4001222	BHL-HFFMMR-100
4001216	BHL-HFFMMR-120
4001235	BHL-HFFMMR-150
4001244	BHL-HFFMMR-180
4001226	BHL-HFFMMR-200