DECLARATION CE DE CONFORMITE / *EC DECLARATION OF CONFORMITY*

Je soussigné, Alexandre ITZKOWITCH, Directeur Général et Responsable Matériovigilance de la société

I undersigned, Alexandre ITZKOWITCH, Managing Director and Materiovigilancy Manager of the company

TECHNOLOGIE MEDICALE
101 rue Vaillant Couturier
93130 NOISY LE SEC
FRANCE

déclare que les dispositifs médicaux de classe **I cités ci-après** sont conformes aux exigences du **règlement européen 2017/745/UE** / *declare that the medical devices of class **I next quoted** comply with the requirements of the **European regulation 2017/745/EU***

Et que les dispositifs médicaux de classe **IIa et IIb cités ci-après** sont conformes aux exigences de la **Directive 93/42CEE** / *and that the medical devices of class **IIa and IIb next quoted** comply with the requirements of **directive 93/42/EEC**.*

Cette déclaration de conformité couvre les dispositifs médicaux tels que spécifiés dans la liste des références produits relatifs à cette déclaration, et n'est valable que pour les dispositifs portant un numéro de série ou de lot.
This declaration of conformity covers the medical devices as specified in the product reference list be longing to this declaration, and is valid only for devices marked with serial or batch number,

Ces dispositifs satisfont aux exigences essentielles de l'Annexe I des textes cités ci-dessus.
These devices fulfil the essential requirements of the Annex I of the texts cited above.

La procédure d'évaluation de la conformité, applicable uniquement pour les dispositifs de classe IIa et IIb, a été établie conformément à l'Annexe II, hors section 4 de la directive 93/42/CEE (certificat n° 28577 rev.8, du LNE/G-MED, numéro d'identification 0459).
The conformity assessment procedure, applicable only for class IIa and IIb medical devices, was established in accordance with Annex II, excluding section 4 of the 93/42/EEC directive (certificate n° 28577 rev.8 of LNE/G-MED, identification number 0459).

Fait à Noisy-Le-Sec, le 26 juin 2023
Made in Noisy-Le-Sec, June 26, 2023

Alexandre ITZKOWITCH

Digitally signed by Grabazei Alexandru
Date: 2025.10.21 14:47:55 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

BOCAL DE RECUEIL /*COLLECTION JAR*

Classe I / ***Class I***

(Documentation technique / *technical documentation* : Bocal de recueil)

IUD-ID de base / *Basic UDI-DI* : 366616623BOCREL

15019	15020	15021	15022	15025	15026	15027	15028	15029	15030	15031	15032	15033	15034	15035
15037	15047	15048	15052	15053	15054	15055	15057	15058	15059	15060	15061	15062	17037	18706
18724	19588	24753	24868											

POCHE DE RECUEIL / *SINGLE USE SUCTION LINER*

Classe I / ***Class I***

(Documentation technique / *technical documentation* : Poche de recueil)

IUD-ID de base / *Basic UDI-DI* : 366616624POCRHZ

11640	11643	11671	15038	15039	15040	15041	15042	15043	15044	15045	15046	15049	15050	15051
17322	17323	17324	22050	22287	22311									

FILTRES / *FILTERS*

Classe I / ***Class I***

(Documentation technique / *technical documentation* : Filtre)

IUD-ID de base / *Basic UDI-DI* : 366616629FILMG

11812	11813	11817	11818											

BOCAL DE SECURITE / *SAFETY JAR*

Classe I / ***Class I***

(Documentation technique / *technical documentation* : Bocal de sécurité)

IUD-ID de base / *Basic UDI-DI* : 366616629BOCSGQ

11693	11731	11733	11738	11740	11774	16987	17031	17032	17151	17630	17664	17758	18753	18754
24620														

CONTROLE-VIDE, STOP-VIDE, SUCEUR/*VACUUM-CONTROL, VACUUM-STOP, SINGLE-USE SUCTION TIP FOR DRAINAGE*

Classe I / ***Class I***

(Documentation technique / *technical documentation* : Contrôle-vide, Stop-vide, MVS & Suceur)

IUD-ID de base / *Basic UDI-DI* : 366616629CVSVKQ

16600	16606	16607	16612	16615	16621	16622								

TUYAU SILICONE D'ASPIRATION / *SILICONE SUCTION HOSE*

Classe I / *Class I*

(Documentation technique / *technical documentation* : Tuyau silicone)

IUD-ID de base / *Basic UDI-DI* : 366616629SILPH

16916														

RACCORDS, TETINES, OLIVES / *FLOWMETER ADAPTOR, NIPPLES ONE-PIECE, NIPPLES TWO-PIECES*

Classe I / *Class I*

(Documentation technique / *technical documentation* : Tétine, Olive, Raccord)

IUD-ID de base / *Basic UDI-DI* : 366616619TORQ9

11170	11429	11430	11431	11532	11535	11537	11540	11541	11542	11543	11547	11622	11623	11897
15294	15295	15298	15299	15323	15324	15326	16584	16585	16586	16587	16588	16589	16590	16591
16592	17023	17348	18047	18533	18723	18728	20039	22128	22455					

RAIL ET GRIFFES / *RAIL AND CLAMPS*

Classe I / *Class I*

(Documentation technique / *technical documentation* : Rail et griffe)

IUD-ID de base / *Basic UDI-DI* : 366616630R&GJ8

11949	15606	15610	15611	15612	15613	15614	15615	15616	15619	15620	15621	15622	15623	15624
15626	15653	15654	15657	15658	15659	15661	15665	15666	15667	15668	15669	15670	15671	15672
15674	15675	15676	15677	15679	15680	15681	15682	15683	15684	15685	15686	15695	15696	15697
15698	15699	15700	15701	15764	17417	17418	17735	18081	18096	18571	18641			

DÉBITMÈTRES À BILLE / *FLOWMETERS WITH FLOATING BALL*

RTM3 – RTM3 DUO

Classe IIa / *Class IIa*

(Documentation technique / *technical documentation* : RTM3)

IUD-ID de base / *Basic UDI-DI* : 366616611RTM3GU

13867	13868	13869	13870	13871	13872	13879	13880	13881	13882	13883	13884	13885	13886	13887
13888	13889	13890	13891	13892	13893	13894	13895	13896	13897	13898	13899	13900	13901	13902
13903	13904	13905	13906	13907	13908	13909	13910	13911	13912	13913	13914	13915	13916	13917
13918	13919	13920	13921	13922	13923	13924	13925	13926	13927	13928	13929	13966	13967	13968
13969	13970	13971	13972	13973	13974	13975	13976	13977	13978	13979	13980	13981	13982	13983
13984	13985	13986	13987	13988	13989	14014	14015	14016	14017	14018	14019	14026	14027	14028
14029	14030	14031	14032	14033	14034	14035	14036	14037	14038	14039	14040	14041	14042	14043
14044	14045	14046	14047	14048	14049	14050	14051	14052	14053	14054	14055	14056	14057	14058
14059	14060	14061	14062	14063	14064	14065	14066	14067	14068	14069	14070	14071	14072	14073
14074	14075	14076	14077	14078	14079	14080	14081	14082	14083	14084	14085	14128	14129	14130
14131	14132	14133	14134	14135	14136	14137	14138	14139	14140	14141	14142	14143	14144	14145
14146	14147	14148	14149	14150	14151	14152	14153	14154	14155	14156	14157	14218	14219	14220
14221	14222	14223	14224	14225	14226	14227	14228	14229	14230	14231	14232	14233	14234	14235
14236	14237	14238	14239	14240	14241	14242	14243	14244	14245	14246	14247	14278	14279	14280
14281	14282	14283	14284	14285	14286	14287	14288	14289	14290	14291	14292	14293	14294	14295
14296	14297	14298	14299	14300	14301	14302	14303	14304	14305	14306	14307	14338	14339	14340
14341	14342	14343	14344	14345	14346	14347	14348	14349	14350	14351	14352	14353	14354	14355
14356	14357	14358	14359	14360	14361	14362	14363	14364	14365	14366	14367	14398	14399	14400
14401	14402	14403	14404	14405	14406	14407	14408	14409	14410	14411	14412	14413	14414	14415
14416	14417	14418	14419	14420	14421	14422	14423	14424	14425	14426	14427	14428	14429	14430
14431	14432	14433	14434	14435	14436	14437	14438	14439	14440	14441	14442	14443	14444	14445
14458	14459	14460	14461	14462	14463	14464	14465	14466	14467	14468	14469	14494	14495	14496
14497	14498	14499	14500	14501	14502	14503	14504	14505	14506	14507	14508	14509	14510	14511
14512	14513	14514	14515	14516	14517	14530	14531	14532	14533	14534	14535	14536	14537	14538
14539	14540	14541	14566	14567	14568	14569	14570	14571	14572	14573	14574	14575	14576	14577
14578	14579	14580	14581	14582	14583	14584	14585	14586	14587	14588	14589	14590	14591	14592
14593	14594	14595	14608	14609	14610	14611	14612	14613	14614	14615	14616	14617	14618	14619
14620	14621	14622	14635	14636	14637	14638	14639	14640	14641	14642	14643	14644	14645	14646
14647	14648	14649	14891	14892	14893	14894	14895	14896	14897	14898	14899	14900	14901	14902
14915	14916	14917	14918	14919	14920	14921	14922	14923	14924	14925	14926	14927	14928	14929
14930	14931	14932	14933	14934	14935	14936	14937	14938	14939	14940	14941	14942	14943	14944
14945	14946	14947	14948	14949	14950	14951	14952	14953	14954	14955	14956	17061	17062	17154
17164	17165	17321	17330	17427	17428	17429	17430	17431	17432	17572	17573	17575	17576	17577
17578	17580	17581	17582	17583	17588	17589	17592	17593	17594	17595	17596	17597	17598	17599
17600	17601	17602	17603	17605	17606	17608	17609	17611	17612	17613	17614	17770	17823	17825
17992	17996	17997	17998	17999	18000	18001	18002	18003	18004	18005	18006	18007	18008	18009
18010	18011	18012	18013	18014	18016	18017	18031	19806	20047	20073	20079	20169	20170	20172
21493	21552	21553	21554	21555	21556	21557	21558	21559	21560	21561	21562	21563	21564	21565
21566	21567	21623	21624	21625	21626	21627	21628	21629	21630	21631	21632	21633	21634	21635
21636	21637	21638	21639	21640	21641	21642	21643	21644	21645	21646	21647	21812	22052	22053
22054	22055	22056	22097	22131	22149	22348	22360	22373	22398	22409	22410	22418	22422	22423
22437	22438	22439	22442	22443	24452	24515	24538	24559	24560	24561	24562	24563	24564	24565
24566	24567	24568	24569	24571	24573	24585	24592	24639	24642	24754	24755	24757	24760	24786
24788	24793	24804	24808	24814	24815	24816	24817	24834	24835	24836	24845	24846	24847	24852
24858	24859	24892	24893	24901	24904	24909	24910	24911						

DÉBITMÈTRES À ORIFICE PRÉCALIBRÉ / *FLOWMETERS WITH PRE-AJUSTED FLOWRATES*

DEBSON TM2

Classe IIa / *Class IIa*

(Documentation technique / *technical documentation* : DEBSON TM2)

IUD-ID de base / *Basic UDI-DI* : 366616612DEBSCP

18098	18099	18100	18101	18102	18103	18106	18107	18108	18109	18132	18133	18134	18135	18136
18137	18138	18139	18140	18141	18142	18143	18144	18146	18147	18148	18149	18150	18151	18152
18153	18154	18155	18156	18157	18158	18159	18160	18161	18162	18163	18164	18165	18166	18167
18168	18169	18170	18171	18172	18173	18174	18175	18176	18177	18178	18179	18180	18181	18182
18183	18184	18185	18186	18187	18188	18190	18191	18192	18193	18194	18195	18196	18197	18198
18199	18200	18201	18202	18203	18204	18205	18206	18207	18208	18209	18210	18211	18212	18213
18214	18215	18216	18217	18218	18219	18220	18221	18222	18223	18224	18225	18226	18227	18228
18229	18230	18231	18232	18233	18234	18235	18236	18237	18238	18239	18240	18241	18242	18243
18244	18245	18246	18247	18248	18249	18250	18251	18252	18253	18254	18255	18256	18257	18258
18259	18262	18263	18264	18265	18266	18267	18268	18269	18270	18271	18272	18273	18274	18275
18278	18279	18280	18281	18282	18283	18284	18285	18286	18287	18288	18289	18290	18291	18292
18293	18294	18295	18296	18297	18298	18299	18300	18301	18302	18303	18304	18305	18306	18307
18308	18309	18310	18311	18312	18313	18314	18315	18383	18384	18385	18387	18388	18389	18390
18584	18585	18586	18587	18588	18589	18590	18591	18592	18593	18594	18595	18596	18597	18598
18599	18617	18618	18619	18620	18621	18622	18696	18708	18710	18711	18712	18713	18714	18716
18717	18718	18719	18720	18721	18722	21477	21483	21584	21585	21586	21587	21588	21589	21590
21591	21592	21593	21594	21595	21596	21597	21598	21599	21600	21601	21602	21603	21604	21605
21606	21607	21608	21609	21610	21611	21612	21613	21614	21615	21616	21617	21618	21619	21620
21621	21622	21813	21814	22327	22338	22364	22368	22376	22377	22440	22441	22444	24552	24554
24555	24556	24557	24558	24572	24802	24814	24843	24848	24849	24853	24857	24861	24862	24867
24897	24898													

DEBITMETRES A ORIFICES PRECALIBRES / *FLOWMETERS WITH PRE-ADJUSTED FLOWRATES*

DEBFLO

Classe IIa / *Class IIa*

(Documentation technique / *technical documentation* : DEBFLO – DEPLUS)

IUD-ID de base / *Basic UDI-DI* : 366616612DEBFBV

20590	20591	20592	20593	20594	20595	20596	20597	20598	20599	20600	20601	20602	20603	20604
20605	20606	20607	20608	20609	20610	20611	20612	20613	20614	20615	20616	20617	20618	20619
20620	20621	20622	20623	20624	20625	20626	20627	20628	20629	20630	20631	20632	20633	20634
20635	20636	20637	20638	20639	20640	20641	20642	20643	20644	20645	20646	20647	20648	20649
20650	20651	20652	20653	20654	20655	20656	20657	20658	20659	20660	20661	20662	20663	20664
20665	20666	20667	20668	20669	20670	20671	20672	20673	20674	20675	20676	20677	20678	20679
20680	20681	20682	20683	20684	20685	20686	20687	20688	20689	20690	20691	20692	20693	20694
20695	20696	20697	20698	20699	20700	20701	20702	20703	20704	20705	20706	20707	20708	20709
20710	20711	20712	20713	20714	20715	20716	20717	20718	20719	20720	20721	20722	20723	20724
20725	20726	20727	20728	20729	20730	20731	20732	20733	20734	20735	20736	20737	20738	20739
20740	20741	20742	20743	20744	20745	20746	20747	20748	20749	20750	20751	20752	20753	20754
20755	20756	20757	20758	20759	20760	20761	20762	20763	20764	20765	20778	20779	20780	20781
20782	20783	20784	20785	20786	20787	20788	20789	20790	20791	20792	20793	20794	20795	20796
20797	20798	20799	20800	20801	20938	20939	20940	20941	20942	20943	20944	20945	20946	20947
20948	20949	20950	20951	20952	20953	20954	20955	20956	20957	20958	20959	20960	20961	20962

20963	20964	20965	20966	20967	20968	20969	20970	20971	20972	20973	20974	20975	20976	20977
20978	20979	20980	20981	20982	20983	20984	20985	20986	20987	20988	20989	20990	20991	20992
20993	20994	20995	20996	20997	20998	20999	21000	21001	22232	22233	22234	22235	22270	22349
22350	22407	22421	22444	22445	24541	24542	24543	24544	24545	24546	24547	24548	24549	24550
24551	24552	24572	22828	22829	22830	22831	22832	22833	22834	22835	22836	22837	22838	22839
22840	22841	22842	22843	22844	22845	22846	22847	22860	24886					

DEBITMETRES A ORIFICES PRECALIBRES / *FLOWMETERS WITH PRE-ADJUSTED FLOWRATES*

DEBPLUS

Classe IIa / *Class IIa*

(Documentation technique / *technical documentation* : DEBFLO – DEPLUS)

IUD-ID de base / *Basic UDI-DI* : 366616612DEBPCH

21002	21003	21004	21005	21006	21007	21008	21009	21010	21011	21012	21013	21014	21015	21016
21017	21018	21019	21020	21021	21022	21023	21024	21025	21026	21027	21028	21029	21030	21031
21032	21033	21034	21035	21036	21037	21038	21039	21040	21041	21042	21043	21044	21045	21046
21047	21048	21049	21050	21051	21052	21053	21054	21055	21056	21057	21058	21059	21060	21061
21062	21063	21064	21065	21066	21067	21068	21069	21070	21071	21072	21073	21074	21075	21076
21077	21078	21079	21080	21081	21082	21083	21084	21085	21086	21087	21088	21089	21090	21091
21092	21093	21094	21095	21096	21097	21098	21099	21100	21101	21102	21103	21104	21105	21106
21107	21108	21109	21110	21111	21112	21113	21114	21115	21116	21117	21118	21119	21120	21121
21122	21123	21124	21125	21126	21127	21128	21129	21130	21131	21132	21133	21134	21135	21136
21137	21138	21139	21140	21141	21142	21143	21144	21145	21146	21147	21148	21149	21150	21151
21152	21153	21154	21155	21156	21157	21158	21159	21160	21161	21162	21163	21164	21165	21166
21167	21168	21169	21170	21171	21172	21173	21174	21175	21176	21177	21190	21191	21192	21193
21194	21195	21196	21197	21198	21199	21200	21201	21202	21203	21204	21205	21206	21207	21208
21209	21210	21211	21212	21213	21350	21351	21352	21353	21354	21355	21356	21357	21358	21359
21360	21361	21362	21363	21364	21365	21366	21367	21368	21369	21370	21371	21372	21373	21374
21375	21376	21377	21378	21379	21380	21381	21382	21383	21384	21385	21386	21387	21388	21389
21390	21391	21392	21393	21394	21395	21396	21397	21398	21399	21400	21401	21402	21403	21404
21405	21406	21407	21408	21409	21410	21411	21412	21413	21568	21569	21570	21571	21572	21573
21574	21575	21576	21577	21578	21579	21580	21581	21582	21583	21837	21838	21839	21840	21841
21842	21843	21844	22011	22127	22274	22375	22404	24553	24844	24850	24851	24854	24855	24856
24860														

FLEXIBLES / *HOSEPIPES*

Classe IIa / *Class IIa*

(Documentation technique / *technical documentation* : Flexible)

IUD-ID de base / *Basic UDI-DI* : 366616640FLEL2

14978	14979	14980	14981	14982	14983	14984	14985	14986	14987	14988	14989	14990	14991	14992
14993	14994	14995	14996	14997	14998	14999	15000	15001	15002	15003	15004	15005	15006	15007
15008	15009	15010	15011	15012	15013	15014	15015	15016	15017	15018	15091	15092	15093	15094
15095	15096	15097	15098	15099	15100	15101	15102	15103	15104	15105	16693	17040	17041	17042
17043	17044	17045	17046	17047	17048	17049	17050	17051	17053	17058	17059	17074	17084	17090
17091	17092	17093	17102	17176	17177	17178	17179	17180	17186	17340	17433	17474	17475	17476
17477	17478	17479	17480	17481	17482	17483	17484	17485	17486	17487	17488	17489	17490	17491
17492	17493	17495	17529	17530	17531	17532	17533	17534	17546	17692	17693	17738	18547	18607

18608	19719	19720	19721	19722	19723	19724	20100	20101	20102	20103	20104	20179	20180	20577
21519	21520	21548	21549	21816	22012	22013	22063	22064	22078	22079	22143	22146	22147	22243
22244	22292	22343	22344	22345	22346	22353	22382	22387	22388	24580	24581	22446	22447	22448
24570	24587	24588	24615	24643	24777	24792	24806	24807	24813	24831	24832	24833	24840	24841
24842	24866	24870	24871	24880	24881	24882	24895	24896	24900	24903				

SWITCH & FLOW SWITCH

Classe IIa / *Class IIa*

(Documentation technique / *technical documentation* : Switch &Flow-switch)

IUD-ID de base / *Basic UDI-DI* : 366616619FSWNR

11600	11616	11617	24583											

HUMIDIFICATEUR / *HUMIDIFIER*

CCO

Classe IIa / *Class IIa*

(Documentation technique / *technical documentation* : Humidificateur)

IUD-ID de base / *Basic UDI-DI* : 366616616HUMMY

18648	22295	22296	22297	22298	22299									

DEDOUBLEURS DE PRISE & RAMPES / *Y CONNECTORS & AMBULANCE PANELS*

Classe IIa / *Class IIa*

(Documentation technique / *technical documentation* : Dédoubleur & rampe)

IUD-ID de base / *Basic UDI-DI* : 366616650DRALD

10001	10002	10003	10005	10006	10007	10016	10017	10018	10019	10021	10025	10026	10027	17169
17622	17632	17678	17707	18483	18484	18485	18486	18487	18488	18489	18490	18491	18492	18493
18572	18614	18659	18715	18725	18726	18727	18785	20075	20184	21508	22246	22372		

ROBINETS DIRECTS / *DIRECT VALVES*

Classe IIa / *Class IIa*

(Documentation technique / *technical documentation* : Robinet direct)

IUD-ID de base / *Basic UDI-DI* : 366616615ROBN3

15286	15287	15288	15336	15337	15338	18735								

REGULATEURS DE VIDE / *VACCUM REGULATOR*

RVTM3

Classe IIa / *Class IIa*

(Documentation technique / *technical documentation* : RVTM3)

IUD-ID de base / *Basic UDI-DI* : 366616620RVT3HV

18792	18793	18794	18795	18796	18797	18798	18799	18800	18801	18802	18803	18804	18805	18806
18807	18808	18809	18810	18811	18812	18813	18814	18815	18816	18817	18818	18819	18820	18821
18822	18823	18824	18825	18826	18827	18828	18829	18830	18831	18832	18833	18834	18835	18836
18837	18838	18839	18840	18841	18842	18843	18844	18845	18846	18847	18848	18849	18850	18851
18852	18853	18854	18855	18856	18857	18858	18859	18860	18861	18862	18863	18864	18865	18866

18867	18868	18869	18870	18871	18872	18873	18874	18875	18876	18877	18878	18879	18880	18881
18882	18883	18884	18885	18886	18887	18888	18889	18890	18891	18892	18893	18894	18895	18896
18897	18898	18899	18900	18901	18902	18903	18904	18905	18906	18907	18908	18909	18910	18911
18912	18913	18914	18915	18916	18917	18918	18919	18920	18921	18922	18923	18924	18925	18926
18927	18928	18929	18930	18931	18932	18933	18934	18935	18936	18937	18938	18939	18940	18941
18942	18943	18944	18945	18946	18947	18948	18949	18950	18951	18952	18953	18954	18955	18956
18957	18958	18959	18960	18961	18962	18963	18964	18965	18966	18967	18968	18969	18970	18971
18972	18973	18974	18975	18976	18977	18978	18979	18980	18981	18982	18983	18984	18985	18986
18987	18988	18989	18990	18991	18992	18993	18994	18995	18996	18997	18998	18999	19000	19001
19002	19003	19005	19006	19007	19008	19009	19010	19011	19012	19013	19014	19015	19016	19017
19018	19019	19020	19021	19022	19023	19024	19025	19026	19027	19028	19029	19030	19031	19032
19033	19034	19035	19036	19037	19038	19039	19040	19041	19042	19043	19044	19045	19046	19047
19048	19049	19050	19051	19052	19053	19054	19055	19056	19057	19058	19059	19060	19061	19062
19063	19064	19065	19066	19067	19068	19069	19070	19071	19072	19073	19074	19075	19076	19077
19078	19079	19080	19081	19082	19083	19084	19085	19086	19087	19088	19089	19090	19091	19092
19093	19094	19095	19096	19097	19158	19159	19160	19161	19162	19163	19164	19165	19166	19167
19168	19169	19170	19171	19172	19173	19174	19175	19176	19177	19178	19179	19180	19181	19182
19183	19184	19185	19186	19187	19188	19189	19190	19191	19192	19193	19194	19195	19196	19197
19198	19199	19200	19201	19202	19203	19204	19205	19206	19207	19208	19209	19210	19211	19212
19213	19214	19215	19216	19217	19218	19219	19220	19221	19222	19223	19224	19225	19226	19227
19228	19229	19338	19339	19340	19341	19342	19343	19344	19345	19346	19347	19348	19349	19350
19351	19352	19353	19354	19355	19356	19357	19358	19359	19360	19361	19362	19363	19364	19365
19366	19367	19368	19369	19370	19371	19372	19373	19374	19375	19376	19377	19378	19379	19380
19381	19382	19383	19384	19385	19386	19387	19388	19389	19390	19391	19392	19393	19394	19395
19396	19397	19398	19399	19400	19401	19402	19403	19404	19405	19406	19407	19408	19409	19410
19411	19412	19413	19414	19415	19416	19417	19418	19419	19420	19421	19422	19423	19424	19425
19426	19427	19555	19556	19563	19564	19565	19566	19567	19568	19569	19570	19571	19572	19573
19574	19645	19734	19735	19736	19868	19869	19870	19871	19872	19873	19874	19875	19876	19877
19878	19879	19880	19881	19882	19883	19884	19885	19886	19887	19888	19889	19890	19891	19892
19893	19894	19895	19896	19897	19898	19899	19900	19901	19902	19903	19904	19958	19959	19960
19961	19962	19963	19964	19965	19966	19967	19968	19969	19970	19971	19972	19973	19974	19975
19976	19977	19978	19979	19980	19981	19982	19983	19984	19985	19986	19987	19988	19989	19990
19991	19992	19993	19994	19995	19996	19997	19998	19999	20000	20001	20002	21478	21513	21649
21650	21651	21652	21653	21654	21655	21656	21657	21658	21659	21660	21661	21662	21663	21664
21665	21666	21667	21668	21669	21670	21671	21672	21673	21674	21675	21676	21677	21678	21679
21680	21681	21682	21683	21696	21697	21698	21699	21700	21701	21702	21703	21704	21705	21706
21707	21708	21709	21710	21711	21712	21713	21714	21715	21716	21717	21718	21719	21720	21721
21722	21723	21724	21725	21726	21727	21728	21729	21730	21731	21732	21733	21734	21735	21736
21737	21738	21739	21740	21741	21742	21743	21744	21745	21746	21747	21748	21749	21750	21751
21752	21753	21754	21755	21756	21757	21758	21759	21760	21761	21762	21763	21764	21765	21766
21767	21768	21769	21770	21771	21772	21773	21774	21775	21776	21777	21778	21779	21780	21781
21782	21783	21784	21785	21786	21787	21788	21789	21790	21791	21792	21793	21794	21795	21796
21797	21798	21799	21800	21801	21802	21803	21811	21855	22110	22111	22112	22113	22114	22115
22116	22117	22118	22119	22120	22121	22271	22332	22333	22334	22335	22361	22365	22366	22367
22381	22383	22419	22420	22887	22888	22889	22890	22891	22892	22893	22894	22895	22896	22897
22898	22899	22900	22901	22902	22903	22904	22905	22906	22907	22908	22909	22910	22911	22912
22913	22914	22915	22916	22917	22918	22919	22920	22921	22922	22923	22924	22925	22926	22927
22928	22929	22930	22931	22932	22933	22934	22935	22936	22937	22938	22939	22940	22941	22942
22943	22944	22945	22946	22947	22948	22949	22950	22951	22952	22953	22954	22955	22956	22957
22958	24514	24616	24617	24618	24619	24803	24809	24810	24811	24826	24827	24876	24877	24878

24879	24884	24885	24894											

SOUPAPES DE JEANNERET / *WATER MANOMETERS*

Classe IIa / *Class IIa*

(Documentation technique / *technical documentation* : Soupape de Jeanneret)

IUD-ID de base / *Basic UDI-DI* : 366616620SDJLX

15079	15080	15081	15082	15083	15084	15106	15107	15108	15109	15110	15111	15112	15113	15114
15115	15116	15117	15118	15119	15120	15121	15122	15123	15124	15125	15126	15127	15128	15129
15130	15131	15132	15133	15134	15135	15136	15137	15138	15139					

VANNES DE VIDE / *DIRECT VACUUM VALVES*

Classe IIa / *Class IIa*

(Documentation technique / *technical documentation* : Vanne de vide)

IUD-ID de base / *Basic UDI-DI* : 366616620VDVN6

10303	10304	10305	11419											

VENTURI TM2

Classe IIa / *Class IIa*

(Documentation technique / *technical documentation* : Venturi TM2)

IUD-ID de base / *Basic UDI-DI* : 366616620VTM2HQ

20206	20207	20208	20209	20210	20211	20212	20213	20214	20215	20216	20217	20218	20219	20220
20221	20222	20223	20224	20225	20226	20227	20228	20229	20230	20231	20232	20233	20234	20235
20236	20237	20238	20239	20240	20241	20242	20243	20244	20245	20246	20247	20248	20249	20250
20251	20252	20253	20254	20255	20256	20257	20258	20259	20260	20261	20262	20263	20264	20265
20266	20267	20268	20269	20270	20271	20272	20273	20274	20275	20276	20277	20278	20279	20280
20281	20282	20283	20284	20285	20286	20287	20288	20289	20290	20291	20292	20293	20294	20295
20296	20297	20298	20299	20300	20301	20302	20303	20304	20305	20306	20307	20308	20309	20310
20311	20312	20313	20314	20315	20316	20317	20318	20319	20320	20321	20322	20323	20324	20325
20326	20327	20328	20329	20330	20331	20332	20333	20334	20335	20376	20377	20378	20379	20380
20381	20382	20383	20384	20385	20386	20387	20388	20389	20390	20391	20392	20393	20394	20395
20396	20397	20398	20399	20400	20401	20402	20403	20404	20405	20406	20407	20408	20409	20410
20411	20412	20413	20414	20415	20416	20417	20418	20419	20420	20421	20422	20423	20424	20425
20426	20427	20428	20429	20430	20431	20432	20433	20434	20435	20436	20437	20438	20439	20440
20441	20442	20443	20444	20445	20446	20447	20448	20449	20450	20451	20452	20453	20454	20455
20456	20457	20458	20459	20460	20461	20462	20463	20464	20465	20466	20467	20468	20469	20470
20471	20472	20473	20474	20475	20516	20517	20518	20519	20520	20521	20522	20523	20524	20525
20526	20527	20528	20529	20530	20531	20532	20533	20534	20535	20536	20537	20538	20539	20540
20541	20542	20543	20544	20545	20546	20547	20548	20549	20550	20551	20552	20553	20554	20555
20556	20557	20558	20559	20560	20561	20562	20563	20564	20565	20566	20567	20568	20569	20570
20571	20572	20573	20574	20575	20578	20579	20580	20581	20582	20583	20584	20585	20586	20587
21972	21973	21974	21975	21976	21977	21978	21979	21980	21981	21982	21983	21984	21985	21986
21987	21988	21989	21990	21991	21992	21993	21994	21995	21996	21997	21998	21999	22000	22001
22002	22003	22018	22019	22020	22021	22022	22023	22024	22025	22026	22027	22028	22029	22030
22031	22032	22033	22034	22035	22036	22037	22038	22039	22040	22041	22042	22043	22044	22045

22046	22047	22048	22049	22126	22369	22959	22960	22961	22962	22963	22964	24883	24899	

DETENDEURS /*PRESSURE REGULATORS*
REGFLOW TM (FINE) - REGSON TM2(FAST) – DETREGTM (HDM, FIX 2)

Classe IIb / *Class IIb*

(Documentation technique / *technical documentation* : Minireg, Regflow-Regson-Detreg)

IUD-ID de base / *Basic UDI-DI* : 366616613DETKM

15232	15233	15234	15235	15236	15237	15238	15239	15240	15262	15263	15264	15265	15266	15267
15268	15269	15339	17188	17189	17190	17191	17194	17195	17196	17197	17198	17199	17200	17201
17202	17203	17204	17205	17206	17207	17208	17209	17210	17214	17215	17216	17217	17218	17219
17220	17221	17222	17223	17224	17225	17226	17227	17228	17229	17230	17231	17232	17233	17234
17235	17236	17237	17238	17239	17240	17241	17242	17243	17245	17246	17247	17248	17249	17250
17251	17252	17253	17254	17257	17258	17373	17516	17541	17542	17584	17585	17590	17691	17762
17771	17777	17778	17780	17810	17822	17830	17835	17993	18043	18045	18080	18086	18097	18396
18397	18398	18399	18400	18401	18402	18403	18404	18405	18406	18407	18408	18409	18410	18411
18412	18413	18414	18415	18416	18417	18418	18419	18420	18421	18422	18423	18424	18425	18426
18428	18429	18430	18431	18434	18435	18436	18437	18438	18439	18440	18441	18442	18443	18444
18445	18447	18448	18449	18450	18451	18453	18454	18455	18456	18457	18458	18459	18460	18461
18462	18463	18464	18465	18466	18467	18468	18469	18470	18471	18472	18473	18475	18529	18543
18544	18545	18546	18548	18549	18550	18551	18552	18553	18554	18555	18556	18557	18558	18559
18560	18561	18562	18563	18564	18565	18567	18568	18569	18582	18613	18623	18633	18657	18658
18695	18707	18770	18771	18772	18773	18774	18775	18776	18777	18790	19482	19644	19653	19654
19682	19687	19711	19714	19715	19718	19727	19810	20055	20076	20080	20087	20105	20109	20113
20114	20156	20183	20187	20204	20588	20589	21501	21804	21805	21806	21807	21808	21809	22065
22066	22067	22091	22093	22130	22141	22150	22151	22152	22153	22154	22155	22231	22247	22273
22275	22280	22293	22309	22312	22320	22324	22325	22326	22339	22356	22359	22363	22374	22401
22402	24453	24584	24745	24764	24765	24766	24812	24824	24825	24887	24888	24889	24890	24891

DETENDEURS /*PRESSURE REGULATORS*
MINIREG (FIX 1 TM)

Classe IIb / *Class IIb*

(Documentation technique / *technical documentation* : Minireg, Regflow-Regson-Detreg)

IUD-ID de base / *Basic UDI-DI* : 366616613MREGGK

15270	15271	15272	15273	15274	15275	15276	15277	15278	15279	18071	18781	18782	18784	19713
19716														

MELANGEURS DE GAZ / *GAZ BLENDERS*
BLENDER TM2

Classe IIb / *Class IIb*

(Documentation technique / *technical documentation* : BLENDER TM2)

IUD-ID de base / *Basic UDI-DI* : 366616614BTM2EB

24534	24589	24590	24591	24593	24594	24595	24596	24597	24598	24599	24600	24607	24608	24610
24611	24612	24613	24614	24741	24776	24819	24820	24821	24822					

La désignation des produits codés par les références listées ci-dessus est disponible chez le fabricant.
The designation of the products scoded by the references quoted above are available at the manufacturer.

Manufacturer's Declaration

TECHNOLOGIE MEDICALE's declaration in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	TECHNOLOGIE MEDICALE
Manufacturer address and contact details	Address: 101 rue Vaillant Couturier, 93130 Noisy le sec, FRANCE Phone number : +33 (0)1 48 45 58 95 E-mail : info@technologiemedicale.com
Single Registration Number (SRN) (if available)	FR-MF-000000498

Authorised Representative name (if applicable)	Non applicable
Authorised Representative address and contact details	Non applicable
Single Registration Number (SRN) (if available)	Non applicable

Notified body name (if applicable)	GMED/Groupe LNE See attached schedule
Notified body number (if applicable)	0459 See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	28577 rev. 8 See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	May 26th, 2024 (included) See attached schedule
End date of extended validity/transition period	December 31, 2028 See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Manufacturer's Declaration

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer 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 Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☒ A QMS in accordance with Article 10(9) MDR is in place.

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

- **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) 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.

Manufacturer's Declaration

Signed for and on behalf of the manufacturer:

TECHNOLOGIE MEDICALE

Noisy-le-Sec, May 13th 2024

Alexandre ITZKOWITCH, CEO

Tel : + 33 (0)1.48.45.28.01
Email : a.itzkowitch@technologiemedicale.com

Manufacturer's Declaration

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Debflo 366616612DEBFBV	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Debplus 366616612DEBPCH	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Debson TM2 366616612DEBSCP	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
RTM3 366616611RTM3GU	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Dédoubleur 366616650DRALD	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Rampe 366616650DRALD	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Flexible 366616640FLEL2	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Humidificateur 366616616HUMMY	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
SWITCH 366616619FSWNR	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
FLOW-SWITCH 366616619FSWNR	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

TECHNOLOGIE MEDICALE

Manufacturer's Declaration

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
RVTM3 366616620RVT3HV	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Soupape de Jeanneret 366616620SDJLX	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Vanne de vide 366616620VDVN6	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Vanne de vide Australie 366616620VDVGHB	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Venturi TM2 366616620VTM2HQ	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Minireg 366616613MREGGK	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Regflow TM 366616613DETKM	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Regson TM2 366616613DETKM	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Detreg TM 366616613DETKM	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Blender TM2 366616614BTM2EB	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable

CERTIFICATE

POİNT TIBBİ CİHAZLAR MEDİKAL GAZ SİSTEMLERİ ELEKTRİK İNŞAAT TİCARET LİMİTED ŞİRKETİ

VELİBABA MAH. MİMAR SİNAN CAD. SAN. SİT. B2 NO:15/6 İÇ KAPI NO:14
PENDİK / İSTANBUL / TÜRKİYE

Has been assessed and found to comply with the requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 9001:2015

The Quality Management System is applicable to:
Kalite Yönetim Sistemi:

PRODUCTION AND SALES OF OXYGEN PLANT, NITROGEN PROTOXIDE PLANT, MEDICAL AIR PLANT, MEDICAL VACUUM PLANT, WASTE GAS EVACUATION PLANT, FLOOR CONTROL AND ALARM UNIT, INTENSIVE CARE UNIT, PATIENT BEDSIDE UNIT, OPERATING ROOM PENDANT, MEDICAL GAS OUTLET REGULATOR, JACK, OXYGEN FLOWMETER, REGULATOR, IV POLE, MONITOR STAND, MULTI-PURPOSE BASKET, OXYGEN PRODUCTION SYSTEM, VIRUS DISINFECTION DEVICE, PATIENT BED, VACUUM JAR, DISPOSABLE VACUUM JAR, PRODUCTION, SALES, INSTALLATION, MAINTENANCE AND REPAIR OF MEDICAL GAS SYSTEMS AND EQUIPMENT

OKSİJEN SANTRALİ, AZOT PROTOKSİT SANTRALİ, MEDİKAL HAVA SANTRALİ, MEDİKAL VAKUM SANTRALİ, ATIK GAZ TAHLİYE SANTRALİ, KAT KONTROL VE ALARM ÜNİTESİ, YOĞUN BAKIM ÜNİTESİ, HASTA YATAK BAŞI ÜNİTESİ, AMELİYATHANE PENDANTI, MEDİKAL GAZ PRİZİ DÜZENLEYİCİ, JAK, OKSİJEN FLOWMETRESİ, REGÜLATÖR, SERUM ASKISI, MONİTÖR SEHPASI, ÇOK AMAÇLI SEPET, OKSİJEN ÜRETİM SİSTEMİ, VİRÜS DEZENFEKSİYON CİHAZI, HASTA YATAĞI, VAKUM KAVANOZU, TEK KULLANIMLIK VAKUM KAVANOZU ÜRETİMİ VE SATIŞI, MEDİKAL GAZ SİSTEMLERİ VE EKİPMANLARI ÜRETİMİ, SATIŞI, KURULUMU, BAKIM VE ONARIMI

Certificate Number: QMS-011200
Belge Numarası: QMS-011200

Initial Certification Date: 03.10.2025
İlk Belgelendirme Tarihi: 03.10.2025

Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 02.10.2026
Belge Geçerlilik Tarihi: 02.10.2026

ACCREDITED
Management Systems
Certification Body
MSCB-135

IQR Certification Approval

IQR INTERNATIONAL CERTIFICATION SERVICES LLC
8 The Green Suite A, Dover, Delaware 19901, USA
www.iqrcert.com | e-posta: info@iqrcert.com

CERTIFICATE

POİNT TIBBİ CİHAZLAR MEDİKAL GAZ SİSTEMLERİ ELEKTRİK İNŞAAT TİCARET LİMİTED ŞİRKETİ

VELİBABA MAH. MİMAR SİNAN CAD. SAN. SİT. B2 NO:15/6 İÇ KAPI NO:14
PENDİK / İSTANBUL / TÜRKİYE

Has been assessed and found to comply with the requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 13485:2016

Medical Devices-Quality Management System is applicable to:
Tıbbi Cihazlar Kalite Yönetim Sistemi

PRODUCTION AND SALES OF OXYGEN PLANT, NITROGEN PROTOXIDE PLANT, MEDICAL AIR PLANT, MEDICAL VACUUM PLANT, WASTE GAS EVACUATION PLANT, FLOOR CONTROL AND ALARM UNIT, INTENSIVE CARE UNIT, PATIENT BEDSIDE UNIT, OPERATING ROOM PENDANT, MEDICAL GAS OUTLET REGULATOR, JACK, OXYGEN FLOWMETER, REGULATOR, IV POLE, MONITOR STAND, MULTI-PURPOSE BASKET, OXYGEN PRODUCTION SYSTEM, VIRUS DISINFECTION DEVICE, PATIENT BED, VACUUM JAR, DISPOSABLE VACUUM JAR

OKSİJEN SANTRALİ, AZOT PROTOKSİT SANTRALİ, MEDİKAL HAVA SANTRALİ, MEDİKAL VAKUM SANTRALİ, ATIK GAZ TAHLİYE SANTRALİ, KAT KONTROL VE ALARM ÜNİTESİ, YOĞUN BAKIM ÜNİTESİ, HASTA YATAK BAŞI ÜNİTESİ, AMELİYATHANE PENDANTI, MEDİKAL GAZ PRİZİ DÜZENLEYİCİ, JAK, OKSİJEN FLOWMETRESİ, REGÜLATÖR, SERUM ASKISI, MONİTÖR SEHPASI, ÇOK AMAÇLI SEPET, OKSİJEN ÜRETİM SİSTEMİ, VİRÜS DEZENFEKSİYON CİHAZI, HASTA YATAĞI, VAKUM KAVANOZU, TEK KULLANIMLIK VAKUM KAVANOZU ÜRETİMİ VE SATIŞI

Certificate Number: 2025/MDQMS/001242 **Initial Certification Date: 03.10.2025**
Belge Numarası: 2025/MDQMS/001242 **İlk Belgelendirme Tarihi: 03.10.2025**

Certification Period: 3 Years **Certificate Validity Date: 02.10.2026**
Belgelendirme Periyodu: 3 Yıl **Belge Geçerlilik Tarihi: 02.10.2026**

ACCREDITED
Management Systems
Certification Body
MSCB-135

IQR Certification Approval

IQR INTERNATIONAL CERTIFICATION SERVICES LLC
8 The Green Suite A, Dover, Delaware 19901, USA
www.iqrcert.com | e-posta: info@iqrcert.com

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Medical Gas Systems
Product Catalogue
Каталог Продукции
Медицинских Газовых Систем

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GAS PLANTS & EQUIPMENT

ГАЗОВЫХ СТАНЦИЯХ & ОБОРУДОВАНИЕ

Code / Код	Product Name / Название продукта
PNT-V-R-TRB-S-X X: DIN, BS, AF Standart	Vacuum Regulator Trump with Precision Spray Operating Range: 0-760 mm Hg Polycarbonate Humidification Bottle 200 cl Турбо Чувствительность точной настройки регулятора вакуума Рабочий диапазон: 0-760 mm Hg Поликарбонат 200 мл в бутылке

Code / Код	Product Name / Название продукта
PNT-FLV-X X: DIN, BS, AF	Oxygen Flowmeter Flow Rate: 0-15 l/min at 4 Bar Polycarbonate Humidification Bottle 200 cl Chrome Plated Brass Body, PC Bottle Cap Расходомер Скорость Потока: 0-15 л/мин

Code / Код	Product Name / Название продукта
PNT-FLV-MP-X X: X: DIN, BS, AF	Oxygen Flowmeter Metal Flow Rate: 0-15 l/min at 4 Bar Polycarbonate Humidification Bottle 200 cl Chrome Plated Brass Body Расходомер Кислорода, Цельный Металл Скорость Потока: 0-15 л/мин

EQUIPMENT ОБОРУДОВАНИЕ

Code / Код	Product Name / Название продукта
PNT-VK-RA	Vacuum Jar with Rail Apparatus - 2 l Вакуумная банка - 2 л

Code / Код	Product Name / Название продукта
PNT-RA	Rail Apparatus for Vacuum Jars Рельсовый аппарат для вакуумных банок

Code / Код	Product Name / Название продукта
PNT-VK-K	Disposable Vacuum Jar with Rail Apparatus - 2 l одноразовая вакуумная банка с насадкой-рейкой - 2 л

Code / Код	Product Name / Название продукта
PNT-SH	Vacuum Silicone Hose 11x7x2 mm Flexible, resistant to breakage and bending Шланг Вакуумный Силиконовый 11x7x2 мм Гибкий, устойчивый к поломке и изгибу

Code / Код	Product Name / Название продукта
PNT-S-K	Catheter Jar Polycarbonate - with Rail Apparatus Катетерные банки

FOR NEW PRODUCTS AND FURTHER INFORMATION PLEASE VISIT OUR WEBSITE:

Paris, le 4 janvier 2024
Paris, January 4th, 2024

Lettre de confirmation émise par l'Organisme Notifié
Notified Body Confirmation Letter
Référence/*Reference :* 39354 rev. 0

[ENGLISH BELOW]

A qui de droit,
Confirmation du statut d'une demande formelle, d'un accord écrit et de la surveillance appropriée dans le cadre du règlement UE 2023/607 modifiant les règlements (UE) 2017/745 et (UE) 2017/746 en ce qui concerne les dispositions transitoires relatives à certains dispositifs médicaux et dispositifs médicaux de diagnostic in vitro.

Cette lettre confirme que, **GMED SAS**, Organisme Notifié désigné au titre du règlement (UE) 2017/745 (ci-après : MDR) et identifié par le numéro **0459** sur NANDO, a reçu une demande formelle de certification conformément à l'annexe VII, section 4.3, premier alinéa, et a signé un accord écrit (contrat) conformément à l'annexe VII, section 4.3, deuxième alinéa dudit Règlement avec le fabricant nommé ci-dessous :

TECHNOLOGIE MEDICALE
101 rue Vaillant Couturier
93130 NOISY-LE-SEC
FRANCE
SRN : FR-MF-000000498

Les dispositifs couverts par la demande formelle et l'accord écrit mentionnés ci-dessus sont identifiés dans les tableaux suivants. Le tableau 1 identifie les dispositifs pour lesquels une demande formelle a été reçue, un accord écrit conclu et pour lesquels GMED SAS est également responsable de la surveillance appropriée des dispositifs correspondants au titre de la directive applicable. Le tableau 2 identifie les dispositifs pour lesquels une demande de RDM a été reçue et un accord écrit conclu, mais pour lesquels GMED SAS n'est pas encore responsable de la surveillance appropriée des dispositifs correspondants au titre de la directive applicable.

Dans le cas de dispositifs couverts par des certificats délivrés au titre de la directive 90/385/CEE (AIMDD) ou de la directive 93/42/CEE (MDD) qui ont expiré après le 26 mai 2021 et avant le 20 mars 2023, sans avoir été retirés, cette lettre confirme également que le fabricant a signé l'accord écrit avant la date d'expiration desdits certificats ou a fourni la preuve qu'une Autorité Compétente d'un État Membre a accordé une dérogation conformément à l'article 59(1) du règlement (UE) 2017/745 ou a demandé conformément à l'article 97(1) du règlement (UE) 2017/745, de mettre en œuvre la procédure d'évaluation de la conformité applicable, avant le 20 mars 2023 pour les dispositifs concernés.

Les délais de transition qui s'appliquent aux dispositifs couverts par la présente lettre, sous réserve que le fabricant continue de respecter les autres conditions spécifiées à l'article 120.3 du Règlement (UE) 2017/745 (amendé par le Règlement (UE) 2023/607), sont indiqués ci-dessous :

- 26 mai 2026 pour les dispositifs implantables sur mesure de classe III
- 31 décembre 2027 pour les dispositifs de classe III et les dispositifs implantables de classe IIb à l'exclusion des technologies bien établies (WET - sutures, agrafes, obturations dentaires, appareils dentaires, couronnes dentaires, vis, coins, plaques, fils, broches, clips et connecteurs)
- 31 décembre 2028 pour les autres dispositifs de classe IIb, de classe IIa, de classe I mis sur le marché à l'état stérile, ayant une fonction de mesurage
- 31 décembre 2028 pour les dispositifs dont l'évaluation de la conformité au titre de la Directive 93/42/CEE ne nécessitait pas l'intervention d'un organisme notifié (par exemple instruments chirurgicaux réutilisables de classe I).

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, ***GMED SAS****, a Notified Body designated against Regulation (EU) 2017/745 (hereafter: MDR) and identified by the number* ***0459*** *on NANDO, has received a formal application for certification in accordance with Annex VII, section 4.3, first subparagraph, and has signed a written agreement (contract) in accordance with Annex VII, section 4.3, second paragraph of the said regulation with the manufacturer named below:*

TECHNOLOGIE MEDICALE
101 rue Vaillant Couturier
93130 NOISY-LE-SEC
FRANCE
SRN : FR-MF-000000498

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the written agreement was concluded by the date of certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- *26 May 2026 for Class III custom-made implantable devices*
- *31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)*
- *31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.*
- *31 December 2028 for devices whose conformity assessment under Directive 93/42/EEC did not require the intervention of a notified body (e.g. class I reusable surgical instruments).*

Pour le compte de GMED SAS,
On behalf of GMED SAS,

DocuSigned by:
Estelle MOENS
E4BC3C03D3E54A3...

Estelle MOENS
Responsable de Département DMA TS
TS AMD Department Manager

Tableau 1 : Dispositifs couverts par la présente lettre et pour lesquels GMED SAS est également responsable de la surveillance appropriée des dispositifs correspondants dans le cadre de la Directive applicable
Table 1: Devices covered by this letter and for which GMED SAS is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive

Device name and/or Basic UDI-DI (under MDR application)	*Risk class of the device according to Annex VIII of Regulation (EU) 2017/745*	*Identification of the device certified under Directive 90/385/EEC or 93/42/EEC and intended to be substituted, if applicable*	*Reference(s) of the certificate(s) under Directive 90/385/EEC or 93/42/EEC*
Debflo 366616612DEBFBV	IIa	Debflo	28577 rev. 8
Debplus 366616612DEBPCH	IIa	Debplus	28577 rev. 8
Debson TM2 366616612DEBSCP	IIa	Debson TM2	28577 rev. 8
RTM3 366616611RTM3GU	IIa	RTM3	28577 rev. 8
Dédoubleur 366616650DRALD	IIa	Dédoubleur	28577 rev. 8
Rampe 366616650DRALD	IIa	Rampe	28577 rev. 8
Flexible 366616640FLEL2	IIa	Flexible	28577 rev. 8
Humidificateur 366616616HUMMY	IIa	Humidificateur	28577 rev. 8
SWITCH 366616619FSWNR	IIa	SWITCH	28577 rev. 8
FLOW-SWITCH 366616619FSWNR	IIa	FLOW-SWITCH	28577 rev. 8

RVTM3 366616620RVT3HV	IIa	RVTM3	28577 rev. 8
Soupape de Jeanneret 366616620SDJLX	IIa	Soupape de Jeanneret	28577 rev. 8
Vanne de vide 366616620VDVN6	IIa	Vanne de vide	28577 rev. 8
Vanne de vide Australie 366616620VDVGHB	IIa	Vanne de vide Australie	28577 rev. 8
Venturi TM2 366616620VTM2HQ	IIa	Venturi TM2	28577 rev. 8
Minireg 366616613MREGGK	IIb	Minireg	28577 rev. 8
IIRegflow TM 366616613DETKM	IIb	IIRegflow TM	28577 rev. 8
Regson TM2 366616613DETKM	IIb	Regson TM2	28577 rev. 8
Detreg TM 366616613DETKM	IIb	Detreg TM	28577 rev. 8
Blender TM2 366616614BTM2EB	IIb	Blender TM2	28577 rev. 8

Tableau 2 : Dispositifs couverts par la présente lettre et pour lesquels GMED SAS n'est pas encore responsable de la surveillance appropriée des dispositifs correspondants dans le cadre de la Directive applicable
Table 2: Devices covered by this letter and for which GMED SAS is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and/or Basic UDI-DI (under MDR application)	*Risk class of the device according to Annex VIII of Regulation (EU) 2017/745*	*Identification of the device certified under Directive 90/385/EEC or 93/42/EEC and intended to be substituted, if applicable*	*Reference(s) of the certificate(s) under Directive 90/385/EEC or 93/42/EEC*
N/A	N/A	N/A	N/A

Historique de révision de la lettre
Confirmation Letter Revision History

Date	Révision/*Revision*	Action
4 janvier 2024 *January 4th, 2024*	39354 rev. 0 *39354 rev. 0*	Première emission *Initial issuance*

Pour toute question concernant le statut ou la validité de cette lettre, veuillez contacter : g-med-certificats@lne-gmed.com
For any query about the status of validity of this letter, please contact : g-med-certificats@lne-gmed.com