

Product conversion in the course of the MDR transition

Dear customers,

As of 15.01.2024, our product groups breathing gas humidifiers, heated breathing sets and humidification chambers have been produced and placed on the market in accordance with the MDR (Regulation EU 2017/745) in compliance with the latest European regulations. This will now be followed by the certification of our other product groups: unheated breathing sets/breathing tubes, respiratory masks, exhalation valves, tube extensions and the WILAflow Elite ventilator.

The MDR certification not only marks a significant milestone in our efforts to offer high-quality and safe medical devices, but also brings significant changes to the labeling of our products. In order to meet the new regulatory and normative requirements, we have revised the labeling of our products in terms of language, symbolism and content. The updates comply with the latest EU regulations and have been carefully designed to meet the highest quality and safety standards.

This means that the following products will be converted to MDR Regulation (EU) 2017/745:

Item number:	Designation:	Date:
	Respiratory masks	
201110	Ventura FFM non-vented, Size Large	September 02, 2024
201111	Ventura FFM non-vented, Size Medium	September 02, 2024
201112	Ventura FFM non-vented, Size Small	September 02, 2024
201113	Ventura FFM CPAP + AAV, Size Small	September 02, 2024
201114	Ventura FFM CPAP + AAV, Size Medium	September 02, 2024
201115	Ventura FFM CPAP + AAV, Size Large	September 02, 2024
201107	Ventura FFM non-vented + AAV, Size Small	September 02, 2024
201108	Ventura FFM non-vented + AAV, Size Medium	September 02, 2024
201109	Ventura FFM non-vented + AAV, Size Large	September 02, 2024

Ventilator for neonates and children

101300	WILAflow Elite - Basic unit with equipment trolley	August 01, 2024
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Breathing tubes

2701361	BT3400 - WILAmEd breathing tube 200 cm	August 01, 2024
2701461	BT3304 - WILAmEd breathing tube 120 cm	August 01, 2024
2701501	BT3291 - WILAmEd breathing tube 30	August 01, 2024
2701661	BT3101 - Breathing tube 180 cm, 555	August 01, 2024
2704461	BT2100 - WILAmEd Flex Lite breathing tube	August 01, 2024
2700021	BT3800 - Breathing tube 90 cm, 999	August 01, 2024
2700531	BT3320 - WILAmEd breathing tube 75cm, 888	August 01, 2024
2701531	BT3307 - Breathing tube gray 60 cm	August 01, 2024
2701551	BT3314 - WILAmEd breathing tube 30 cm	August 01, 2024
2701731	BT3309 - WILAmEd breathing tube 270 cm	August 01, 2024

Exhalation valves

260618	WILAsilent exhalation valve	September 02, 2024
260620	WILAsilent 2 exhalation valve	September 02, 2024
260622	WILAsilent 2 in bag	September 02, 2024

Tube extensions

2701021	Tube extension (15cm, 22M/15F-15M)	September 02, 2024
2701031	Tube extension (15cm, 22M/15F-22F)	September 02, 2024
2705001	Tube extension (20cm, 22M/15F-15M)	September 02, 2024
2705011	Tube extension (20cm, 22M/15F-22F)	September 02, 2024

Breathing sets unheated

271706	BTS6068 Single-hose system prisma VENT	August 01, 2024
270096	WILAmEd Disposable NO - Kit	August 01, 2024
270178	BTS334 - WILAmEd ventilation system	August 01, 2024
270180	BTS338 - WILAmEd tubing system	August 01, 2024
270182	BTS301 - WILAmEd tubing system	August 01, 2024
270315	BTS331 - Single-hose system, Astral	August 01, 2024
270329	BTS200 - WILAmEd ventilation system	August 01, 2024

270330	BTS100 - WILAmEd ventilation system	August 01, 2024
270334	BTS315 - WILAmEd Disposable ventilation	August 01, 2024
270337	BTS227 - WILAmEd double tube system	August 01, 2024
270347	BTS810 - CCough hose system	August 01, 2024
270348	PROCEDURE-PACK (REF 271191 / BTS834)	August 01, 2024
270349	PROCEDURE-PACK - (REF 271191 / BTS834)	August 01, 2024
270359	BTS805 - Coaxial single-hose system	August 01, 2024
270366	BTS357 - WILAmEd Disposable emergency ventilation	August 01, 2024
270375	BTS304 - WILAmEd double tube system	August 01, 2024
270422	BTS326 - WILAmEd tubing system	August 01, 2024
270437	BTS317 - WILAmEd double tube system	August 01, 2024
270439	BTS606 - WILAmEd for Legendair	August 01, 2024
270447	BTS323 - WILAmEd Disposable ventilation	August 01, 2024
270480	Breathing set unheated, 1-tube	August 01, 2024
270483	BTS363 - WILAmEd single tube system	August 01, 2024
270518	BTS383 - AIRniva single-hose system	August 01, 2024
270520	WILAmEd infant flow supply line	August 01, 2024
270523	BTS220 - WILAmEd double tube system	August 01, 2024
270526	BTS221 - WILAmEd single tube system	August 01, 2024
270537	BTS148 - WILAmEd single tube system	August 01, 2024
270542	BTS229 - WILAmEd single tube system	August 01, 2024
270558	BTS398 - Breathing set unheated, single hose	August 01, 2024
270582	BTS250 - WILAmEd single tube system	August 01, 2024
270583	BTS3116 - WILAmEd single tube system	August 01, 2024
270584	BTS3117 - Disposable hose Ventilo	August 01, 2024
270585	BTS3118 - WILAmEd double tube system	August 01, 2024
270593	BTS254 - WILAmEd double tube system	August 01, 2024
270594	BTS6056 10mm double hose adapter kit	August 01, 2024
270595	BTS178 - WILAmEd double tube system	August 01, 2024
270598	BTS256 - WILAmEd single tube system	August 01, 2024
270603	BTS265 - WILAmEd double tube system	August 01, 2024
270610	BTS3130 - WILAmEd single tube system	August 01, 2024
270616	BTS184 - WILAmEd double tube system	August 01, 2024
270624	BTS3138 - Breathing set unheated for Astral	August 01, 2024

270627	BTS278 - WILAmEd single tube system	August 01, 2024
270628	BTS3141 - WILAmEd single tube system	August 01, 2024
270650	BTS3155 - WILAmEd Trilogy Leakage	August 01, 2024
270652	PROCEDURE-PACK (REF 270931 /BTS3301)	August 01, 2024
270653	BTS820 - WILAmEd single tube system	August 01, 2024
270655	BTS3157 - WILAmEd Trilogy Leakage	August 01, 2024
270666	BTS286 - WILAmEd single tube system	August 01, 2024
270667	BTS287 - WILAmEd single tube system	August 01, 2024
270677	BTS1103 - WILAmEd double tube	August 01, 2024
270685	BTS3172 - Breathing set unheated, single hose	August 01, 2024
270692	BTS3178 - Breathing set unheated for EOVE E	August 01, 2024
270693	BTS298 - WILAmEd disposable double tube	August 01, 2024
270715	BTS1130 - WILAmEd single tube system	August 01, 2024
270722	BTS3204 - WILAmEd HFO Kit for Leoni Plus	August 01, 2024
270724	BTS3207 - WILAmEd double tube	August 01, 2024
270757	BTS3216 - WILAmEd single tube system	August 01, 2024
270764	BTS1189 - WILAmEd single tube system	August 01, 2024
270773	BTS1196 - WILAmEd breathing set, 120 cm, 10	August 01, 2024
270775	BTS1199 - WILAmEd Transport ventilation	August 01, 2024
270783	BTS1206 - WILAmEd single tube system	August 01, 2024
270784	BTS1207 - WILAmEd single tube system	August 01, 2024
270792	BTS3224 - WILAmEd disposable double tube	August 01, 2024
270798	BTS3228 - WILAmEd tubing system	August 01, 2024
270867	BTS850 - Coaxial single-hose system	August 01, 2024
270931	BTS3301 hose system ComfCough	August 01, 2024
271001	BTS311 - WILAmEd single tube system	August 01, 2024
271002	BTS801 - WILAmEd single tube system	August 01, 2024
271003	BTS300 - WILAmEd one-way ventilation	August 01, 2024
271005	BTS360 - WILAmEd double tube system	August 01, 2024
271006	BTS367 - WILAmEd ventilation system	August 01, 2024
271010	BTS319 - WILAmEd double tube system	August 01, 2024
271011	BTS359 - WILAmEd single tube system	August 01, 2024
271015	BTS333 - WILAmEd single tube system	August 01, 2024
271017	BTS147 - WILAmEd disposable tube	August 01, 2024

271018	BTS3270 - WILAmEd single tube system	August 01, 2024
271019	BTS370 - WILAmEd single tube system	August 01, 2024
271021	BTS290 - WILAmEd single tube system	August 01, 2024
271022	BTS228 - WILAmEd single tube system	August 01, 2024
271024	BTS101 - Double hose system 120cm, 10	August 01, 2024
271025	BTS212 - WILAmEd single tube system	August 01, 2024
271029	BTS321 - WILAmEd single tube system	August 01, 2024
271035	BTS210 - WILAmEd double tube system	August 01, 2024
271040	BTS217 - WILAmEd single-tube system	August 01, 2024
271120	BTS3103 - WILAmEd Disposable emergency	August 01, 2024
271127	BTS1225 - WILAmEd disposable tubing system	August 01, 2024
271129	BTS2122 - WILAmEd single tube system	August 01, 2024
271130	BTS2123 - WILAmEd single tube system	August 01, 2024
271131	BTS3240 - WILAmEd single tube system	August 01, 2024
271133	BTS3241 - WILAmEd tubing system	August 01, 2024
271136	BTS2127 - Breathing set unheated, single hose	August 01, 2024
271162	BTS435 - WILAmEd single tube system	August 01, 2024
271191	BTS834 - WILAmEd tubing system	August 01, 2024
271192	PROCEDURE-PACK - (REF 270931 / BTS3301)	August 01, 2024
271201	BTS3312 - Single hose system 180cm	August 01, 2024
271214	BTS3339 - WILAmEd ventilation system	August 01, 2024
271249	BTS3390 - WILAmEd single tube system	August 01, 2024
271251	BTS2199 - WILAmEd single tube system	August 01, 2024
271513	BTS843 - Breathing set unheated, double hose	August 01, 2024
271514	BTS844 - WILAmEd double tube system	August 01, 2024
271517	WILAmEd expiratory valve disposable	August 01, 2024
271520	BTS3318 - WILAmEd tubing system	August 01, 2024
271541	BTS3369 - WILAmEd double tube system	August 01, 2024
271546	BTS3379 - WILAmEd single tube system	August 01, 2024
271548	BTS3386 - WILAmEd single tube system	August 01, 2024
271559	BTS2208 - WILAmEd single tube system	August 01, 2024
271561	BTS3394 - WILAmEd single tube system	August 01, 2024
271562	BTS3395 - WILAmEd double tube	August 01, 2024
271564	BTS3397 - Breathing set unheated, single hose	August 01, 2024

271576	BTS1318 - WILAmEd double tube system	August 01, 2024
271577	BTS1317 - WILAmEd single tube system	August 01, 2024
271580	BTS3420 - Single-hose system	August 01, 2024
271583	BTS1325 - Double hose system for TV1	August 01, 2024
271584	BTS1324 - WILAmEd single tube system	August 01, 2024
271589	BTS1319 - WILAmEd CPAP Adapter K	August 01, 2024
271596	BTS3418 - Double hose system for VX8	August 01, 2024
271597	BTS3419 - WILAmEd double tube system	August 01, 2024
271598	BTS2220 - WILAmEd double tube system	August 01, 2024
271599	BTS2237 - WILAmEd single tube system	August 01, 2024
271612	BTS2238 - Single-hose system for Astral	August 01, 2024
271633	BTS2244 - One-way vision system	August 01, 2024
271640	BTS6042 Double hose system	August 01, 2024
271643	BTS8058 double hose system	August 01, 2024
271645	BTS6045 Single-hose system for EO	August 01, 2024
271646	BTS8059 Single-hose system for EO	August 01, 2024
271649	BTS3443 Double hose system	August 01, 2024
271652	BTS8061 One-way hose system	August 01, 2024
271654	BTS3449 Coaxial hose system 22mm	August 01, 2024
271655	BTS3448 Coaxial hose system 22mm	August 01, 2024
271662	BTS2246 Single-hose system Eove E0-150	August 01, 2024
271670	BTS3457 One-way hose system V800, V68	August 01, 2024
271687	BTS8076 Breathing set unheated, single tube	August 01, 2024
271688	BTS6058 Single hose system EOVE, 15mm	August 01, 2024
271699	Exhalation valve kit for Astral	August 01, 2024
271701	BTS3460 single-hose system, 22 mm	August 01, 2024
271716	BTS8108 Single-hose system, Legendair	August 01, 2024
271719	BTS8113 single-hose system; CC & CC2	August 01, 2024
271720	BTS2255 Expiratory valve one-way	August 01, 2024
275315	BTS619 - Single-hose system, Astral	August 01, 2024
2701701	BTS302 - WILAmEd disposable tubing system	August 01, 2024
270161	BTS3120 - WILAmEd breathing tube	August 01, 2024
270162	BTS3402 - WILAmEd breathing tube	August 01, 2024
270169	BTS3300 - WILAmEd breathing tube	August 01, 2024

270479	BTS8102 WILAmed disposable tubing system W	August 01, 2024
270503	BTS4041 Incubator extension 40cm	August 01, 2024
271678	BTS6053 Helix single hose system, 15mm	August 01, 2024
271679	BTS8072 Helix single-hose system, 22mm	August 01, 2024
271682	BTS6055 Helix single-hose system, 15mm	August 01, 2024
271683	BTS8075 Helix single-hose system, 22mm	August 01, 2024
271626	BTS3432 Double hose system HELIX	August 01, 2024
271620	BTS2242 HELIX double hose system	August 01, 2024
271725	BTS8114 Helix single-hose system, 22mm	August 01, 2024
271726	BTS6069 Helix single-hose system, 15mm	August 01, 2024
271669	Active Exhalation Valve Kit (AEV Kit)	August 01, 2024
271743	BTS6072 Connecting hose 15mm, 60cm	August 01, 2024
271733	BTS8116 Luisa single hose system 180cm	August 01, 2024
271734	BTS6074 Luisa single-hose system, 15mm	August 01, 2024
271737	BTS8118 Double hose system for Luisa	August 01, 2024
271750	BTS1356 Double hose system for Airborne	August 01, 2024
270249	BTS3507 - WILAmed tubing system	August 01, 2024
271745	BTS6077 Double hose system TEV, 15mm	August 01, 2024
271749	BTS8122 Single hose system TLN, 22mm	August 01, 2024
271744	BTS8120 Double hose system TEV, 22mm	August 01, 2024
271691	BTS8077 Connection kit for Mukostar	August 01, 2024
271732	BTS6073 Double hose system for Luisa	August 01, 2024
271603	BTS2225 - WILAmed double tube system	August 01, 2024
271756	BTS3480 - Luisa double hose system	August 01, 2024
271757	BTS2259 - Luisa double hose system	August 01, 2024

Of course, the relevant contact person in our sales team will be happy to answer any questions you may have.

Yours sincerely, [WILAmed GmbH](#)