

Certificate of Compliance

Device Type

Serial Number

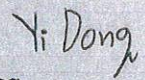
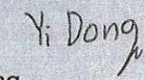
Bellavista 1000e

MB470044

Routine Electrical Safety Test Report

Visual check			Result
No Housing Damage? No Connector Damage? Device Label correct?			OK
Tests according to	EN 60601-1		
Measurement	Measured Value	Limit	Result
Protective Conductor Continuity [R_{PE}]	+0.067Ohm	<0.100Ohm	OK
Insulation Resistance Measurement [R_{NS}] (Referencing EN 62353, sub-clause 5.3.4)	>+310.0MOhm	>2.000MOhm	OK
Earth Leakage Current Measurement Normal Condition [I_{PE-NC}]	+0.181mA	<0.500mA	OK
Earth Leakage Current Measurement Single Fault Condition [I_{PE-SFC}]	+0.288mA	<1.000mA	
Touch Current Normal Condition [I_{HL-NC}]	+001.0μA	<100.0μA	OK
Touch Current Single Fault Condition [I_{HL-SFC}]	+176.1μA	<0.500mA	
Supply Voltage	+238.7V	Not applicable	OK
Test Voltage Dielectric Strength [VDC] (Referencing EN 50514, sub-clause 5.2)	+02.28kV	Not applicable	OK
Function Test			OK
Measurement Device	Type	Manufacturer	Software
	SECUTEST 0751/601 / SIII	GOSSEN-METRAWATT	V7.39

The device is compliant with technical specifications and has passed all tests mentioned above after final assembling (end of line).

	Date	Signed
Routine Electrical Safety Test	13.12.24	 Name: Yi Dong
Final Control	16.12.24	 Name: Yi Dong
Commissioning by manufacturing	16.12.24	 Name: Joseph Teo

Certificate of Compliance

Device Type	Serial Number
Bellavista 1000e	MB470042

Routine Electrical Safety Test Report

Visual check			Result
No Housing Damage? No Connector Damage? Device Label correct?			OK
Tests according to	EN 60601-1		
Measurement	Measured Value	Limit	Result
Protective Conductor Continuity [R_{PE}]	+0.075Ohm	<0.100Ohm	OK
Insulation Resistance Measurement [R_{INS}] (Referencing EN 62353, sub-clause 5.3.4)	>+310.0MOhm	>2.000MOhm	OK
Earth Leakage Current Measurement Normal Condition [I_{PE-NC}]	+0.181mA	<0.500mA	OK
Earth Leakage Current Measurement Single Fault Condition [I_{PE-SFC}]	+0.286mA	<1.000mA	
Touch Current Normal Condition [I_{HL-NC}]	+001.0μA	<100.0μA	OK
Touch Current Single Fault Condition [I_{HL-SFC}]	+175.3μA	<0.500mA	
Supply Voltage	+238.3V	Not applicable	OK
Test Voltage Dielectric Strength [VDC] (Referencing EN 50514, sub-clause 5.2)	+02.28kV	Not applicable	OK
Function Test			OK
Measurement Device	Type SECUTEST 0751/601 / SIII	Manufacturer GOSSEN-METRAWATT	Software V7.39

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	Date	Signed
Routine Electrical Safety Test	13.12.24	Yi Dong Name: Yi Dong
Final Control	16.12.24	Yi Dong Name: Yi Dong
Commissioning by manufacturing	16.12.24	 Name: Joseph Teo

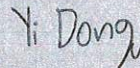
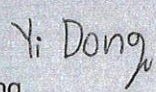
Certificate of Compliance

Device Type	Serial Number
Bellavista 1000e	MB470034

Routine Electrical Safety Test Report

Visual check			Result
No Housing Damage? No Connector Damage? Device Label correct?			OK
Tests according to	EN 60601-1		
Measurement	Measured Value	Limit	Result
Protective Conductor Continuity [R_{PE}]	+0.076Ohm	<0.100Ohm	OK
Insulation Resistance Measurement [R_{DS}] (Referencing EN 62353, sub-clause 5.3.4)	>+310.0MOhm	>2.000MOhm	OK
Earth Leakage Current Measurement Normal Condition [I_{PE-NC}]	+0.179mA	<0.500mA	OK
Earth Leakage Current Measurement Single Fault Condition [I_{PE-SFC}]	+0.290mA	<1.000mA	
Touch Current Normal Condition [I_{HL-NC}]	+001.0μA	<100.0μA	OK
Touch Current Single Fault Condition [I_{HL-SFC}]	+173.5μA	<0.500mA	
Supply Voltage	+237.8V	Not applicable	OK
Test Voltage Dielectric Strength [V_{DC}] (Referencing EN 50514, sub-clause 5.2)	+02.28kV	Not applicable	OK
Function Test			OK
Measurement Device	Type	Manufacturer	Software
	SECUTEST 0751/601 / SIII	GOSSEN-METRAWATT	V7.39

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	Date	Signed
Routine Electrical Safety Test	13.12.24	 Name: Yi Dong
Final Control	16.12.24	 Name: Yi Dong
Commissioning by manufacturing	16.12.24	 Name: Joseph Teo

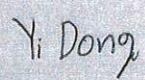
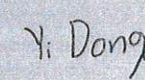
Certificate of Compliance

Device Type	Serial Number
Bellavista 1000e	MB470024

Routine Electrical Safety Test Report

Visual check			Result
No Housing Damage? No Connector Damage? Device Label correct?			OK
Tests according to	EN 60601-1		
Measurement	Measured Value	Limit	Result
Protective Conductor Continuity [R_{PE}]	+0.073Ohm	<0.100Ohm	OK
Insulation Resistance Measurement [R_{INS}] (Referencing EN 62353, sub-clause 5.3.4)	>+310.0MOhm	>2.000MOhm	OK
Earth Leakage Current Measurement Normal Condition [I_{PE-NC}]	+0.177mA	<0.500mA	OK
Earth Leakage Current Measurement Single Fault Condition [I_{PE-SFC}]	+0.287mA	<1.000mA	
Touch Current Normal Condition [I_{HL-NC}]	+001.0μA	<100.0μA	OK
Touch Current Single Fault Condition [I_{HL-SFC}]	+171.5μA	<0.500mA	
Supply Voltage	+238.1V	Not applicable	OK
Test Voltage Dielectric Strength [V_{DC}] (Referencing EN 50514, sub-clause 5.2)	+02.28kV	Not applicable	OK
Function Test			OK
Measurement Device	Type SECUTEST 0751/601 / SIII	Manufacturer GOSSEN-METRAWATT	Software V7.39

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	Date	Signed
Routine Electrical Safety Test	13.12.24	 Name: Yi Dong
Final Control	16.12.24	 Name: Yi Dong
Commissioning by manufacturing	16.12.24	 Name: Joseph Teo

Certificate of Compliance

Device Type

Serial Number

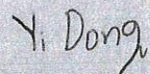
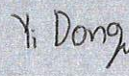
Bellavista 1000e

MB470026

Routine Electrical Safety Test Report

Visual check			Result
No Housing Damage? No Connector Damage? Device Label correct?			OK
Tests according to	EN 60601-1		
Measurement	Measured Value	Limit	Result
Protective Conductor Continuity [R_{PE}]	+0.072Ohm	<0.100Ohm	OK
Insulation Resistance Measurement [R_{INS}] (Referencing EN 62353, sub-clause 5.3.4)	>+310.0MOhm	>2.000MOhm	OK
Earth Leakage Current Measurement Normal Condition [I_{PE-NC}]	+0.179mA	<0.500mA	OK
Earth Leakage Current Measurement Single Fault Condition [I_{PE-SFC}]	+0.285mA	<1.000mA	
Touch Current Normal Condition [I_{HL-NC}]	+001.0μA	<100.0μA	OK
Touch Current Single Fault Condition [I_{HL-SFC}]	+173.8μA	<0.500mA	
Supply Voltage	+238.8V	Not applicable	OK
Test Voltage Dielectric Strength [V_{DC}] (Referencing EN 50514, sub-clause 5.2)	+02.28kV	Not applicable	OK
Function Test			OK
Measurement Device	Type SECUTEST 0751/601 / SIII	Manufacturer GOSSEN-METRAWATT	Software V7.39

The device is compliant with technical specifications and has passed all tests mentioned above after final assembling (end of line).

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Final Control	16.12.24	 Name: Yi Dong
Commissioning by manufacturing	16.12.24	 Name: Joseph Teo

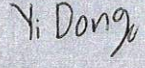
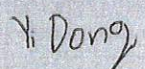
Certificate of Compliance

Device Type	Serial Number
Bellavista 1000e	MB470035

Routine Electrical Safety Test Report

Visual check			Result
No Housing Damage? No Connector Damage? Device Label correct?			OK
Tests according to	EN 60601-1		
Measurement	Measured Value	Limit	Result
Protective Conductor Continuity [R_{PE}]	+0.069Ohm	<0.100Ohm	OK
Insulation Resistance Measurement [R_{INS}] (Referencing EN 62353, sub-clause 5.3.4)	>+310.0MOhm	>2.000MOhm	OK
Earth Leakage Current Measurement Normal Condition [I_{PE-NC}]	+0.185mA	<0.500mA	OK
Earth Leakage Current Measurement Single Fault Condition [I_{PE-SFC}]	+0.295mA	<1.000mA	
Touch Current Normal Condition [I_{HL-NC}]	+000.9µA	<100.0µA	OK
Touch Current Single Fault Condition [I_{HL-SFC}]	+179.4µA	<0.500mA	
Supply Voltage	+238.2V	Not applicable	OK
Test Voltage Dielectric Strength [V_{DC}] (Referencing EN 50514, sub-clause 5.2)	+02.28kV	Not applicable	OK
Function Test			OK
Measurement Device	Type SECUTEST 0751/601 / SIII	Manufacturer GOSSEN-METRAWATT	Software V7.39

The device is compliant with technical specifications and has passed all tests mentioned above after final assembling (end of line).

	Date	Signed
Routine Electrical Safety Test	13.12.24	 Name: Yi Dong
Final Control	16.12.24	 Name: Yi Dong
Commissioning by manufacturing	16.12.24	 Name: Joseph Teo

Declaration of Conformity

MDR – Reg EU 2017/745

0312-001-018-R Rev.10

Effective: 02JAN2024

CRF#: 2023-149

Document Number:	DC-IMT-01-EU	Revision:	05
Technical Document Number:	TD-IMT-01		

(bg) Декларация за съответствие Регламент за медицински изделия • (hr) Izjava o sukladnosti Uredba o medicinskim proizvodima • (cs) Prohlášení o shodě • (da) Overensstemmelseserklæring • (nl) Verklaring van conformiteit • (et) Vastavusdeklaratsioon • (fi) Vaatimustenmukaisuusvakuutus Lääkintälaiteasetus • (fr) Déclaration de conformité • (de) Konformitätserklärung • (el) Δήλωση συμμόρφωσης • (hu) Megfelelőségi nyilatkozat • (it) Dichiarazione di conformità Regolamento sui dispositivi medici • (lv) Atbilstības deklarācija • (lt) Atitikties deklaracija Medicinos priemonių reglamentas • (pl) Deklaracja zgodności Rozporządzenie • (pt) Declaração de conformidade • (ro) Declarație de conformitate • (sk) Vyhlásenie o zhode • (sl) zjava o skladnosti Uredba EU o medicinskih pripomočkih • (es) Declaración de conformidad Informe del dispositivo medico • (sv) Försäkran om överensstämmelse

Legal Manufacturer Законен производител/ Zakonski proizvođač/ Oprávněný výrobce/ Juridisk producent/ Wettelijke fabrikant/ Seaduslik tootja/ Oikeudellinen valmistaja/ Fabricant legal/ Rechtmäßiger Hersteller/ Νόμιμος κατασκευαστής/ Jogszerű gyártó/ Produttore legale/ Likumīgais ražotājs/ Teisėtas gamintojas/ Producent prawny/ Fabricante legal/ Fabricant legal/ Zákonný výrobca/ Zakoniti proizvajalec/ Fabricante legal/ Godkänd tillverkare	Vyaire Medical, Inc. - 26125 North Riverwoods Blvd., Mettawa, IL 60045, USA
SRN Сериен номер/ SR broj/ SRN/ SRN/ SRN/ SRN/ SRN/ SRN/ SRN/ Egyedi regisztrációs szám (SRN)/ SRN/ SRN/ Unikalusis registracijos numeris/ Niepowtarzalny numer rej/ NUR/ NRS/ SRN/ Enotna registrska številka/ SRN/ SRN	Vyaire Medical Inc. - Manufacturer - US-MF- 000008254
Product Продукт/ Proizvod/ Produkt/ Produkt/ Namen/ Toode/ Tuote/ Produit/ Produkt/ Προϊόν/ Termék/ Prodotto/ Produkts/ Gaminys/ Produkt/ Produto/ Produs/ Produkt Izdelek/ Producto/ Produkt	bellavista™ 1000 bellavista™ 1000neo bellavista™ 1000e iFlow 200S Adult/Pediatric Proximal Flow Sensor iFlow 40S Neonatal/Infant Pediatric Proximal Flow Sensor
Product Codes Продуктови кодове/ Kodovi proizvoda/ Produktové kódy/ Produktkoder/ Productcodes/ Tootekoodid/ Tuotekoodit/ Codes produits/ Produktcodes/ Κωδικοί προϊόντων/ Termékkódok/ Codici prodotto/ Produkta kods/ Gaminų kodai/ Kody produktów/ Códigos	See Attachment Вижте прикачения файл/ Pogledajte prilog/ Viz příloha/ Se bilag/ Zie bijlage/ Vt lisa/ Katso liite/ Voir la pièce jointe/ Siehe Anhang/ Δείτε το

Declaration of Conformity MDR – Reg EU 2017/745

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Technical Document Number:	TD-IMT-01		

de produto/ Codurile produsului/ Produktové kódy/ Šifre izdelka/ Códigos de product/ Produktkoder	συννημμένο/ Lásd a mellékletet/ Vedere l'allegato/ Skatīt pielikumu/ Žr. Priedą/ Patrz załącznik/ Consultar anexo/ A se vedea atașamentul/ Pozrite si prílohu/ Glejte prilogo/ Ver archivo adjunto/ Se bilagan
Product Codes Продуктови кодове/ Kodovi proizvoda/ Produktové kódy/ Produktkoder/ Productcodes/ Tootekoodid/ Tuotekoodit/ Codes produits/ Produktcodes/ Κωδικοί προϊόντων/ Termékkódok/ Codici prodotto/ Produkta kods/ Gaminų kodai/ Kody produktów/ Códigos de produto/ Codurile produsului/ Produktové kódy/ Šifre izdelka/ Códigos de product/ Produktkoder	See Attachment Вижте прикачения файл/ Pogledajte prilog/ Viz příloha/ Se bilag/ Zie bijlage/ Vt lisa/ Katso liite/ Voir la pièce jointe/ Siehe Anhang/ Δείτε το συννημμένο/ Lásd a mellékletet/ Vedere l'allegato/ Skatīt pielikumu/ Žr. Priedą/ Patrz załącznik/ Consultar anexo/ A se vedea atașamentul/ Pozrite si prílohu/ Glejte prilogo/ Ver archivo adjunto/ Se bilagan
EMDN Codes EMDN кодове/ EMDN kodovi/ Kódy EMDN/ EMDN-koder/ EMDN- codes/ EMDN koodid/ EMDN-koodit/ Codes EMDN/ EMDN-Codes/ Κωδικοί EMDN/ EMDN-kódok/ Codici EMDN/ EMDN kod/EMDN kodai/ Kody EMDN/ Códigos EMDN/ Codurile EMDN/ Kódy EMDN/ Šifre EMDN/ Códigos de EMDN/ EMDN-koder	See attachment Вижте прикачения файл/ Pogledajte prilog/ Viz příloha/ Se bilag/ Zie bijlage/ Vt lisa/ Katso liite/ Voir pièce jointe/ Siehe Anhang/ Δείτε το συννημμένο/ Lásd a mellékletet/ Vedere l'allegato/ Skatīt pielikumu/ Žr. Priedą/ Patrz załącznik/ Consultar anexo/ A se vedea atașamentul/ Pozrite si prílohu/ Glejte prilogo/ Ver archivo adjunto/ Se bilagan

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Authorized Representative Упълномощен представител/ Ovlaštēni predstavnik/ Autorizovaný zástupce/ Autoriseret repræsentant/ Geautoriseerd vertegenwoordiger/ Volitatud esindaja/ Valtuutettu edustaja/ Représentant agréé/ Bevollmächtigter Vertreter/ Εξουσιοδοτημένος αντιπρόσωπος/ Meghatalmazott képviselő/ Rappresentante autorizzato/ Pilnvarotais pārstāvis/ Įgaliojasis atstovas/ Upoważniony przedstawiciel/ Representante autorizado/ Reprezentant autorizat/ Autorizovaný zástupca/ Pooblaščen zastopnik/ Representante autorizado/ Auktoriserad representant	Emergo Europe – Westervoortsedijk 60, 6827 AT Arhem The Netherlands
Authorized Representative SRN Упълномощен представител SRN/ Ovlaštēni predstavnik SRN/ Autorizovaný zástupce SRN/ Autoriseret repræsentant SRN/ Geautoriseerd vertegenwoordiger SRN/ Volitatud esindaja unikaalne registreerimisnumber/ Valtuutetun edustajan SRN-numero/ SRN du Représentant agréé SRN/ Bevollmächtigter Vertreter SRN/ Ενιαίος αριθμός καταχώρισης (SRN) εξουσιοδοτημένου αντιπροσώπου/ Meghatalmazott képviselő egyedi regisztrációs száma/ SRN del rappresentante autorizzato/ Pilnvarotā pārstāvja SRN numurs/ Įgaliojojo atstovo SRN/ Upoważniony przedstawiciel SRN/ Representante autorizado SRN/ SRN reprezentant autorizat/ Autorizovaný zástupca SRN/ Identifikator SRN za pooblaščenega zastopnika/ SRN del representante autorizado/ Auktoriserad representant SRN	NL-AR-00000116
General applicable directives Общи приложими директиви/ Opće primjenjive uredbe/ Obecně platné směrnice/ Generelt gældende direktiver/ Algemene toepasselijke richtlijnen/ Kohaldatavad ülddirektiivid/ Yleiset soveltuvat direktiivit/ Directives générales applicables/ Allgemein geltende	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 for medical devices Регламент (ЕС) 2017/745 на Европейския парламент и на Съвета от 5 април 2017 г. за медицински изделия Uredba (EU) 2017/745 Europskog parlamenta i Vijeća od 5. travnja 2017. o medicinskim proizvodima Nařízení Evropského parlamentu a Rady (EU) 2017/745 ze dne 5. dubna 2017 o zdravotnických prostředcích Europa-Parlamentets og Rådets forordning (EU) 2017/745 af 5. april 2017 om medicinsk udstyr Verordening (EU) 2017/745 voor medische hulpmiddelen van het Europees Parlement en de Raad van 5 april 2017 Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määrus (EL) 2017/745 meditsiiniseadmete kohta Euroopan parlamentin ja neuvoston asetetus (EU) 2017/745 lääkintälaitteista, annettu 5. päivänä huhtikuuta 2017

Declaration of Conformity

MDR – Reg EU 2017/745

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Technical Document Number:	TD-IMT-01		

Richtlinien/ Γενικές ισχύουσες οδηγίες/ Általánosán alkalmazandó irányelvek/ Direttive generali applicabili/ Vispārpiemērojamās direktīvas/ Bendrai taikomi teisės aktai/ Ogólnie stosowane dyrektywy/ Diretivas gerais aplicáveis/ Directive generale aplicabile/ Všeobecné platné smernice/ Spoločne veljavne directive/ Directivas generales aplicables/ Allmänna tillämpliga direktiv	Règlement (UE) 2017/745 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux Verordnung (EU) 2017/745 des Europäischen Parlaments und des Rates vom 5. April 2017 für Medizinprodukte Κανονισμός (ΕΕ) 2017/745 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 5ης Απριλίου 2017 για τα ιατροτεχνολογικά προϊόντα Az Európai Parlament és a Tanács (EU) 2017/745 rendelete (2017. április 5.) orvostechnikai eszközök alapján Regolamento (UE) 2017/745 del Parlamento europeo e del Consiglio del 5 aprile 2017 sui dispositivi medici Eiropas Parlamenta un Padomes 2017. gada 5. aprīļa Regula (ES) 2017/745 par medicīnas ierīcēm 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamentas (ES) 2017/745 dėl medicinos priemonių Rozporządzenie Parlamentu Europejskiego i Rady (UE) 2017/745 z dnia 5 kwietnia 2017 r. dotyczące wyrobów medycznych Regulamento (UE) 2017/745 do Parlamento Europeu e do Conselho de 5 de abril de 2017 relativo a dispositivos médicos Regulamentul (UE) 745/2017 Parlamentului European și al Consiliului din 05 aprilie 2017 pentru dispozitivele medicale Nariadenie (EÚ) 2017/745 európskeho parlamentu a Rady z 5. apríla 2017 o zdravotníckych pomôckach Uredba (EU) 2017/745 Evropskega parlamenta in Sveta o medicinskih pripomočkih z dne 5. aprila 2017 Reglamento (UE) 2017/745 del Parlamento Europeo y del Consejo del 5 de abril de 2017 para dispositivos médicos Europaparlamentets och rådets förordning (EU) 2017/745 av den 5 april 2017 för medicintekniska enheter
Notified Body Нотифициран орган/ Nadležno tijelo/ Notifikovaný organ/ Bemyndiget organ/ Aangemelde instantie / Teavitatud asutus/ Ilmoitettu laitos/ Organisme notifié/ Benannte Stelle/ Κοινοποιημένος οργανισμός/ Bejelentett szerv/ Organismo notificato/ Pilnvarotā iestāde/ Notifikuotoji įstaiga/ Jednostka notyfikowana/ Organismo notificado/ Organism notifiat/ Notifikovaný organ/ Priglašeni organ/ Organismo notificado/ Anmält organ	BSI Group The Netherlands B.V. - Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands; NB 2797
EC Certificate(s) Сертификат(и) на ЕО/ EZ certifikat/ Certifikáty ES/ EU-certifikat(er)/ EG-certificaa-	Expiration Date Срок на годност/ Datum isteka valjanosti/ Datum vypršení platnosti/ Udløbsdato/
	MDR 734803 2027-04-21

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certificaten/ EÜ sertifikaat (sertifikaadid)/ EY:n todistukset/ Certificat(s) CE/ EG-Zertifikat(e)/ Πιστοποιητικό(α) ΕΚ/ EK-tanúsítvány (ok)/ Certificati CE/ EK sertifikāts(-i)/ EB sertifikatas (-ai)/ Świadectwo(-a) CE/ Certificado(s) CE/ Certificat(e) CE/ Certifikát (certifikáty) ES/ Potrdilo(a) ES/ Certificado(s) de CE/ EU-certifikat	Vervaldatum / Kõlblikkusaeg/ Voimassaolon päättymispäivä/ Date de péremption/ Ablaufdatum/ Ημερομηνία λήξης/ Lejárati idő/ Data di scadenza/ Derīguma termiņš/ Galiojimo pabaigos data/ Data wygaśnięcia ważności/ Data de validade/ Data expirării/ Dátum expirácie/ Rok uporabnosti/ Fecha de caducidad/ Utgångsdatum	
Annex Приложение/ Prilog/ Příloha/ Tilføjelse/ Bijlage/ Lisa/ Liite/ Annexe/ Anlage/ Παράρτημα/ Függelék/ Allegato/ Pielikums/ Notifikuotoji įstaiga/ Priedas/ Załącznik/ Anexa/ Príloha/ Priloga/ Anexo/ Annex		Annex IX, Chapters I and III
Quality System Certificate Сертификат за система за Качество/ Certificat sustava kvalitete/ Certifikát systému jakost/ Kvalitetssystem-certifikat/ Certificaat kwaliteitssysteem/ Kvaliteedi-süsteemi sertifikaat/ Laatujärjestelmän todistus/ Certificat du système qualité/ Qualitätssystemzertifikat/ Πιστοποιητικό συστήματος ποιότητας/ Mi-nő-ség-biz-to-sí-tá-si rendszer tanúsítványa/ Certificato del sistema di qualità/ Kvalitātes sistēmas sertifikāts/ Kokybės sistemos sertifikatas/ Certyfikat systemu jakości/ Certificado do sistema de qualidade/ Certificatul sistemului de calitate/ Certifikát systému kvality/ Potrdilo o sistemu kakovosti/ Certificado del sistema de calidad/ Certifikat för kvalitetssystem	Expiration Date Срок на годност/ Datum isteka valjanosti/ Datum vypršení platnosti/ Udløbsdato/ Vervaldatum/ Kõlblikkusaeg/ Voimassaolon päättymispäivä/ Date de péremption/ Ablaufdatum/ Ημερομηνία λήξης/ Lejárati idő/ Data di scadenza/ Derīguma termiņš/ Galiojimo pabaigos data/ Data wygaśnięcia ważności/ Data de validade/ Data expirării/ Dátum expirácie/ Rok uporabnosti/ Fecha de caducidad/ Utgångsdatum	FM 555355 2027-01-02

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Full Quality System Система за пълно качество/ Cjeloviti sustav kvalitete/ Kompletní systém řízení kvality/ Komplet kvalitetssystem/ Volledig kwaliteitssysteem/ Täielik kvaliteedisüsteem/ Täysimittainen laatu järjestelmä/ Système qualité complet/ Vollständiges Qualitätssystem/ Σύστημα πλήρους ποιότητας/ Teljes minőségirányítási rendszer/ Sistema di qualità complete/ Pilnīgas kvalitātes sistēma/ Visiško kokybės užtikrinimo Sistema/ Pełny system jakości/ Sistema de qualidade complete/ Sistem de calitate complet/ Systém plnej kvality/ Popoln sistem kakovosti/ Sistema de calidad complete/ Fullt kvalitetssystem	ISO 13485:2016
Other applicable directive Друга приложима Директива/ Druge primjenjive uredbе/ Jiná platná směrnice/ Andet gældende direktiv/ Andere toepasselijke richtlijn/ Muu kohaldatav direktiiv/ Muu soveltuva direktiivi/ Autre directive applicable/ Andere anwendbare Richtlinie/ Άλλη ισχύουσα οδηγία/ Egyéb vonatkozó irányelv/ Altra direttiva applicabile/ Cita piemērojama direktīva/ Kita taikoma direktyva/ Inne stosowne dyrektywy/ Outra diretiva aplicável/ Altă directivă aplicabilă/ Iná platná smernica/ Druga veljavna direktiva/ Otra Directiva applicable/	ROHS Directive: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on restriction of the use of certain hazardous substances in electrical and electronic equipment (Only include this on <u>electrical and electronic devices</u>) Директива ROHS: Директива 2011/65/ЕС на Европейския парламент и на Съвета от 8 юни 2011 г. относно ограничението за употребата на определени опасни вещества в електрическото и електронното оборудване Direktiva ROHS: Direktiva 2011/65/EU Europskog parlamenta i Vijeća od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi Směrnice ROHS: Směrnice 2011/65/EU Evropského parlamentu a Rady ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních RoHS-direktivet: Europa-Parlamentets og Rådets direktiv 2011/65/EU af 8. juni 2011 om begrænsning af brugen af visse farlige stoffer i elektrisk og elektronisk udstyr ROHS-richtlijn: Richtlijn 2011/65/EU van het Europees Parlement en de Raad van 8 juni 2011 betreffende beperking van het gebruik van bepaalde gevaarlijke stoffen in elektrische en elektronische apparatuur RoHS-i direktiiv: Euroopa Parlamendi ja nõukogu 8. juuni 2011. aasta direktiiv 2011/65/EL teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes ROHS-direktiivi: 8. päivänä kesäkuuta 2011 annettu Euroopan parlamentin ja neuvoston direktiivi 2011/65/EU tiettyjen vaarallisten aineiden sähkö- ja elektroniikkalaitteissa käytön rajoittamisesta Directive ROHS: Directive 2011/65/UE du Parlement européen et du Conseil du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques

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Annat tillämpligt direktiv	ROHS-Richtlinie: Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 über die Beschränkung der Verwendung bestimmter gefährlicher Substanzen in elektrischen und elektronischen Geräten Οδηγία ROHS: Οδηγία 2011/65/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 8ης Ιουνίου 2011 σχετικά με τον περιορισμό της χρήσης ορισμένων επικίνδυνων ουσιών σε ηλεκτρικό και ηλεκτρονικό εξοπλισμό ROHS irányelv: Az Európai Parlament és a Tanács 2011/65/EU irányelve (2011. június 8.) egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról Direttiva ROHS: direttiva 2011/65/UE del Parlamento europeo e del Consiglio dell'8 giugno 2011 relativa alla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche ROHS direktiva: Eiropas Parlamenta un Padomes 2011. gada 8. jūnija direktīva 2011/65/ES par noteiktu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās Pavojingų medžiagų naudojimo apribojimo direktyva: 2011 m. birželio 8 d. Europos Parlamento ir Tarybos direktyva 2011/65/ES dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo Dyrektywa ROHS: Dyrektywa Parlamentu Europejskiego i Rady 2011/65/UE z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym Diretiva ROHS: Directiva 2011/65/UE do Parlamento Europeu e do Conselho, de 8 de Junho de 2011, relativa à restrição do uso de determinadas substâncias perigosas em equipamentos eléctricos e electrónicos Directiva ROHS: Directiva UE 65/2011 a Parlamentului European și al Consiliului din 08 iunie 2011 privind restricționarea utilizării anumitor substanțe periculoase în echipamentele electrice și electronice Smernica ROHS: Smernica 2011/65/EÚ európskeho parlamentu a Rady z 8. júna 2011 o obmedzení použitia určitých nebezpečných látok v elektrických a elektronických zariadeniach Direktiva ROHS: Direktiva 2011/65/EU Evropskega parlamenta in Sveta o omejevanju uporabe nekaterih nevarnih snovi v električni in elektronski opremi z dne 8. junija 2011 Directiva ROHS: Directiva 2011/65/UE del Parlamento Europeo y del Consejo del 8 de junio de 2011 relativa a la restricción del uso de ciertas sustancias peligrosas en aparatos eléctricos y electrónicos ROHS-direktiv: Europaparlamentets och rådets direktiv 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning
DOC Expiration Date	This DOC is valid for all products produced from date of issuance to 01/02/2027 (MM/DD/YYYY)

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DOC Срок на годност/ Datum isteka valjanosti izjave o skladnosti/ Datum vypršení platnosti dokumentu/ DOC-udløbsdato/ DOC- vervaldatum/ Vastavusdeklaratsiooni aegumiskuupäev/ Asiakirjan voimassaolon päättymispäivä/ Date d'expiration du document/ DOK.- Ablaufdatum/ Ημερομηνία λήξης εγγράφου/ Megfelelési bizonyítvány lejárat ideje/ Data di scadenza DOC/ DOC Derīguma termiņš/ Dokumento galiojimo pabaigos data/ Data wygaśnięcia ważności Deklaracji zgodności/ Data de validade da DC/ Data expirării DC/ Dátum expirácie DOC/ Rok uporabnosti DOC/ Fecha de caducidad del DOC/ DOC utgångsdatum	Този документ е валиден за всички продукти, произведени от датата на издаване до 01/02/2027 (MM/DD/TTTT). Ova izjava o skladnosti valjana je za sve proizvode proizvedene od datuma izdavanja do 01/02/2027 (MM/DD/GGGG). Tento dokument je platný pro všechny výrobky vyrobené od data vydání do 01/02/2027 (MM/DD/RRRR) Dette dokument gælder for alle produkter, der er fremstillet fra udstedelsesdatoen til 01/02/2027 (MM/DD/AAAA) Dit DOC is geldig voor alle producten die zijn geproduceerd vanaf de datum van uitgifte tot 01/02/2027 (MM/DD/JJJJ) See vastavusdeklaratsioon kehtib kõigi toodete jaoks, mis on toodetud alates väljaandmise kuupäevast kuni 01/02/2027 (KK/PP/AAAA) Tämä asiakirja on voimassa kaikille tuotteille, jotka on tuotettu julkaisupäivän ja 01/02/2027 (KK/PP/VVVV) välillä. Ce document est valide pour tous les produits fabriqués à partir de la date d'émission à 01/02/2027 (MM/JJ/AAAA) Dieses DOK. ist für alle Produkte gültig, die ab dem Ausstellungsdatum bis zum 01/02/2027 (MM/TT/JJJJ) produziert wurden Το παρόν έγγραφο ισχύει για όλα τα προϊόντα που παράγονται από την ημερομηνία έκδοσης έως την 01/02/2027 (MM/HH/EEEE) Ez a Megfelelési bizonyítvány minden olyan termékre érvényes, amelyeket a kibocsátás időpontjától a feltüntetett dátumig tartó időszakban állítottak elő: 01/02/2027 ÉÉÉÉ/HH/NN) Questo DOC è valido per tutti i prodotti realizzati dalla data di emissione al 01/02/2027 (MM/GG/AAAA) Šis DOC ir derīgs visiem produktiem, kas ražoti no izdošanas datuma līdz 01/02/2027 (MM/DD/GGGG) Šis dokumentas galioja visiems gaminiams, pagamintiems nuo išleidimo datos iki 01/02/2027 (MMMM/MM/DD) Niniejsza deklaracja zgodności jest ważna dla wszystkich produktów wyprodukowanych od daty wydania do 01/02/2027 (MM/DD/RRRR) Esta DC é válida para todos os produtos produzidos desde a data de emissão até 01/02/2027 (DD/MM/AAAA) Acest DC este valabil pentru toate produsele fabricate de la data emiterii către 01/02/2027 (ZZ/LL/AAAA) Toto DOC platí pre všetky produkty vyrobené odo dňa vydania do 01/02/2027 (MM/DD/RRRR) Ta DOC velja za vse izdelke, proizvedene od datuma izdaje do 01/02/2027 (MM/DD/LLLL)
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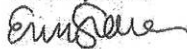
	Este DOC es válido para todos los productos producidos desde la fecha de emisión hasta 01/02/2027 (DD/MM/AAAA) Detta DOC är giltigt för alla produkter som producerats från utfärdandedatumet till 01/02/2027 (MM/DD/ÅÅÅÅ)
We, the manufacturer hereby declare under sole responsibility that the products listed in this document are in conformity with the General Safety and Performance Requirements of Annex I and meets the Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 for medical devices. The medical devices are manufactured under control of ISO 13485:2016 Quality Management System.¹	


Electronically signed by: Terrie
McDaniel
Reason: I approve this document
Date: May 30, 2024 12:08 CDT

Terrie McDaniel, Vice President
Global Quality Assurance, Regulatory Affairs and
Clinical/PPRC

San Antonio, TX USA 30-May-2024

Date and Place



Electronically signed by: Erin
Salbilla
Reason: I approve this document
Date: May 30, 2024 08:57 CDT

Erin Salbilla
Sr. Director Quality

Mettawa, IL USA 30-May-2024

Date and Place

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Attachment

(bg) Прикачен файл / (hr) Prilog / (cs) Příloha / (da) Bilag / (nl) Bijlage / (et) Lisa / (fi) Liite / (fr) Pièce jointe / (de) Anhang / (el) Συνημμένο / (hu) Melléklet / (it) Allegato / (lv) Pielikums / (lt) Priedas / (pl) Załącznik / (pt) Anexo / (ro) Atașament / (sk) Príloha / (sl) Priloga / (es) Archivo adjunto / (sv) Bilaga

Device Listing

Списък на изделията / Popis proizvoda / Seznam prostředků / Produktoversigt / Apparaatvermelding / Seadmete loend / Laiteluettelo / Liste des dispositifs / Geräteliste / Καταχώριση συσκευής / Az eszköz listázása / Elenco dispositivi / Ierīces uzskaitījums / Priemonių sąrašas / Lista urządzeń / Listagem de dispositivos / Listarea dispozitivelor / Zoznam pomôcok / Seznam pripomočkov / Lista de dispositivos / Enhetslista

Product Code ¹	Basic UDI-DI ²	Description ³	EU Class ⁴	Rule(s) ⁵	EMDN Code ⁶	NB Number ⁷	Technical Document ⁸
301.100.000	0190752TDI MT0112BFJ	bellavista™ 1000	IIB	12	Z120301 0504	2797	TD-IMT-01
301.100.060	0190752TDI MT0112BFJ	bellavista™ 1000neo	IIB	12	Z120301 0504	2797	TD-IMT-01
301.100.100	0190752TDI MT0112BFJ	bellavista™ 1000e	IIB	12	Z120301 0504	2797	TD-IMT-01
301.328.020	0190752TDIM T0122AMVB	iFlow 200S Adult/Pediatric Proximal Flow Sensor	Ia	2	Z1203010 585	2797	TD-IMT-01
301.470.020	0190752TDIM T0122AMVB	iFlow 40S Neonatal/Infant Proximal Flow Sensor	Ia	2	Z1203010 585	2797	TD-IMT-01

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EMDN ode ²	EMDN Term ³	Intended Purpose ³
Z1203010504	ADULT AND PAEDIATRIC/NEONATAL PULMONARY VENTILATORS	The bellavista ventilators were developed for ventilating adult and pediatric patients and, optionally, neonatal patients as of a tidal volume of ≥2 mL. The device is intended for use in clinics and institutional facilities where medically trained professionals are available for attending to the patient. The device can be used at the bedside, as well as for transferal within a facility, when a patient is in need of oxygen.
Z1203010585	Pulmonary ventilators for Hospital Use - Consumables	The iFlow 200S and 40S are intended to be used as a device to measure continuous bi-directional patient air flow and airway pressure with bellavista ventilators. The iFlow 200 S is intended to be used only by appropriately trained personnel and can be used for the following types of ventilation: • Life supporting ventilation and non-life supporting ventilation • Invasive and non-invasive ventilation • Stationary and during intra-hospital patient transportation

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1 Translation

(bg) Ние, производителят, декларираме с настоящото единствено отговорността, че продуктите, изброени в настоящия документ, са в съответствие с общите изисквания за безопасност и работа на приложение I и отговарят на Регламент 2017/745 на Европейския парламент и на Съвета от 5 април 2017 за медицински изделия. Медицинските изделия са произведени под контрола на системата за управление на качеството ISO 13485:2016.

(hr) Mi, proizvođač, ovime izjavljujemo pod isključivom odgovornošću da su proizvodi navedeni u ovom dokumentu u skladu s općim zahtjevima sigurnosti i učinkovitosti utvrđenima u Prilogu I. Uredbe 2017/745 Europskog parlamenta i Vijeća od 5. travnja 2017. o medicinskim proizvodima i da su u skladu s navedenom Uredbom. Medicinski proizvodi proizvedeni su u skladu sa sustavom upravljanja kvalitetom prema normi ISO 13485:2016.

(cs) My, výrobce tímto prohlašujeme na svou výhradní odpovědnost, že produkty uvedené v tomto dokumentu jsou v souladu s obecnými požadavky na bezpečnost a funkční způsobilost uvedenými v příloze I a splňují nařízení Evropského parlamentu a Rady 2017/745 ze dne 5. dubna 2017 o zdravotnických prostředcích. Zdravotnické prostředky jsou vyrobeny pod kontrolou systému řízení kvality ISO 13485:2016.

(da) Producenten erklærer sig hermed eneansvarlig for, at de produkter, der er anført i dette dokument, er i overensstemmelse med de generelle sikkerheds- og præstationskrav i bilag I og overholder Europa-Parlamentets og Rådets forordning 2017/745 af 5. april 2017 om medicinsk udstyr. Det medicinske udstyr er fremstillet i overensstemmelse med ISO 13485:2016 Kvalitetssikringssystem.

Wij, de fabrikant, verklaren hierbij onder onze volledige verantwoordelijkheid dat de producten die in dit document worden genoemd in overeenstemming zijn met de Algemene veiligheids- en prestatievereisten van Bijlage I en voldoen aan de Verordening 2017/745 voor medische hulpmiddelen van het Europees Parlement en de Raad van 5 april 2017. De medische hulpmiddelen worden vervaardigd in overeenstemming met het ISO 13485:2016-kwaliteitsbeheersysteem.

(nl) Wij, de fabrikant, verklaren hierbij onder onze volledige verantwoordelijkheid dat de producten die in dit document worden genoemd in overeenstemming zijn met de Algemene veiligheids- en prestatievereisten van Bijlage I en voldoen aan de Verordening 2017/745 voor medische hulpmiddelen van het Europees Parlement en de Raad van 5 april 2017. De medische hulpmiddelen worden vervaardigd in overeenstemming met het ISO 13485:2016-kwaliteitsbeheersysteem.

(et) Meie tootjana kinnitame, et vastutame selle eest, et käesolevas dokumendis loetletud tooted vastavad I lisa üldistele ohutus- ja toimivusnõuetele ning Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määrusele 2017/745 meditsiiniseadmete kohta. Meditsiiniseadmed on toodetud kvaliteedijuhtimissüsteemi ISO 13485: 2016 kontrolli all.

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(fi) Valmistaja vakuuttaa täten yksinomaisella vastuullaan, että tässä asiakirjassa luetellut tuotteet ovat liitteen I yleisten turvallisuus- ja suorituskykyvaatimusten mukaisia ja että ne täyttävät Euroopan parlamentin ja neuvoston lääkintälaitesetus 2017/745, joka on annettu 5. päivänä huhtikuuta 2017. Lääkintälaitteet on valmistettu ISO 13485:2016 -standardin mukaisen laadunhallintajärjestelmän valvonnassa.

(fr) Nous soussignés, fabricant, déclarons, sous notre entière responsabilité, que les produits listés dans ce document sont conformes exigences générales en matière de sécurité et de performances de l'Annexe I et qu'ils satisfont au Règlement (UE) 2017/745 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux. Les dispositifs médicaux sont fabriqués sous le contrôle du système de gestion de la qualité ISO 13485:2016.

(de) Der Hersteller erklärt hiermit in alleiniger Verantwortung, dass die in diesem Dokument aufgeführten Produkte den allgemeinen Sicherheits- und Leistungsanforderungen von Anhang I entsprechen und die Verordnung 2017/745 des Europäischen Parlaments und des Rates vom 5. April 2017 für Medizinprodukte erfüllen. Die Fertigung der Medizinprodukte erfolgt unter Kontrolle mit dem Qualitätsmanagementsystem gemäß ISO 13485:2016.

(el) Εμείς, ο κατασκευαστής, δηλώνουμε διά του παρόντος με αποκλειστική ευθύνη ότι τα προϊόντα που αναφέρονται στο παρόν έγγραφο συμμορφώνονται με τις Γενικές απαιτήσεις ασφάλειας και απόδοσης του Παραρτήματος I και πληρούν τον κανονισμό 2017/745 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 5ης Απριλίου 2017 για τα ιατροτεχνολογικά προϊόντα. Τα ιατροτεχνολογικά προϊόντα κατασκευάζονται υπό τον έλεγχο του Συστήματος διαχείρισης ποιότητας ISO 13485:2016.

(hu) Gyártóként saját felelősségünkre kijelentjük, hogy az ebben a dokumentumban felsorolt termékek megfelelnek az I. melléklet általános biztonsági és teljesítményi követelményeinek, és megfelelnek az orvostechnikai eszközökre vonatkozó, 2017 április 5-i 2017/745 európai parlamenti és tanácsi rendeletnek. Az orvostechnikai eszközöket az ISO 13485:2016 minőségirányítási rendszer szerint gyártjuk.

(it) Il produttore dichiara sotto la propria responsabilità che i prodotti elencati in questo documento sono conformi ai requisiti generali di sicurezza e di prestazione di cui all'allegato I e soddisfano il regolamento 2017/745 del Parlamento europeo e del Consiglio del 5 aprile 2017 sui dispositivi medici. I dispositivi medici sono prodotti sotto controllo del sistema di gestione della qualità ISO 13485:2016.

(lv) Mēs, ražotājs, ar šo vienīgi uz savu atbildību deklarējam, ka šajā dokumentā nosauktie produkti atbilst I pielikuma vispārīgajām drošuma un veiktspējas prasībām un izpilda Eiropas Parlamenta un Padomes 2017. gada 5. aprīļa Regulā 2017/745 par medicīnas ierīcēm ietvertās prasības. Medicīnas ierīces tiek ražotas ISO 13485:2016 Kvalitātes pārvaldības sistēmas uzraudzībā.

Declaration of Conformity

MDR – Reg EU 2017/745

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(lt) Mes, gamintojas, prisiimdami visą atsakomybę patvirtiname, kad šiam dokumente išvardyti gaminiai atitinka I priedo bendruosius saugos ir veiksmingumo reikalavimus ir 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos Reglamento (ES) 2017/745 dėl medicinos priemonių reikalavimus. Medicinos priemonės yra pagamintos taikant ISO 13485:2016 „Kokybės vadybos sistemos“ kontrolę.

(pl) My, producent, niniejszym deklarujemy na wyłączną odpowiedzialność, że produkty wymienione w niniejszym dokumencie są zgodne z ogólnymi wymogami bezpieczeństwa i funkcjonowania Załącznika I i spełniają przepisy rozporządzenia 2017/745 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. dla wyrobów medycznych. Wyroby medyczne są produkowane pod kontrolą systemu zarządzania jakością ISO 13485:2016.

(pt) Nós, o fabricante, declaramos pelo presente e sob a nossa exclusiva responsabilidade que os produtos indicados neste documento estão em conformidade com os Requisitos gerais de segurança e desempenho do Anexo I e que cumprem o Regulamento 2017/745 do Parlamento Europeu e do Conselho de 5 de abril de 2017 relativo a dispositivos médicos. Os dispositivos médicos são fabricados sob o controlo do Sistema de gestão de qualidade ISO 13485:2016.

(ro) Fabricantul declară prin prezenta pe propria răspundere că produsele enumerate în acest document sunt în conformitate cu Cerințele Generale referitoare la Performanță și Siguranță ale Anexei I și respectă Regulamentul 745/2017 al Parlamentului European și al Consiliului din 05 aprilie 2017 pentru dispozitive medicale. Dispozitivele medicale sunt fabricate sub controlul Sistemului de Gestionare a Calității 13485:2016.

(sk) My, výrobca, týmto vyhlasujem na svoju vlastnú zodpovednosť, že produkty uvedené v tomto dokumente spĺňajú požiadavky na všeobecnú bezpečnosť a výkon prílohy I a spĺňajú požiadavky nariadenia 2017/745 európskeho parlamentu a Rady z 5. apríla 2017 o zdravotníckych pomôckach. Zdravotnícke pomôcky sa vyrábajú pod dohľadom systému manažmentu kvality ISO 13485:2016.

(sl) Kot proizvajalec na lastno odgovornost navajamo, da so izdelki, navedeni v dokumentu, skladni s splošnimi zahtevami glede varnosti in učinkovitosti v Prilogi I ter skladni z Uredbo 2017/745 Evropskega parlamenta in Sveta o medicinskih pripomočkih z dne 5. aprila 2017. Medicinski pripomočki so izdelani skladno s standardom ISO 13485:2016 Sistem za zagotavljanje kakovosti.

(es) Nosotros, el fabricante declaramos bajo la responsabilidad exclusiva que los productos que figuran en este documento cumplen con los Requisitos generales de seguridad y rendimiento del Anexo I y que cumplen con el Reglamento 2017/745 del Parlamento Europeo y del Consejo del 5 de abril de 2017 para dispositivos médicos. Los dispositivos médicos se fabrican bajo el control del sistema de gestión de calidad ISO 13485:2016.

(sv) Vi, tillverkaren, intygar härmed på eget ansvar att de produkter som anges i detta dokument överensstämmer med de allmänna säkerhets- och prestationskraven i bilaga I och uppfyller

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Europaparlamentets och rådets förordning 2017/745 av den 5 april 2017 för medicintekniska enheter.
De medicintekniska enheterna är tillverkade under kontroll av kvalitetshanteringssystemet
ISO 13485:2016.

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Product Codes	Basic UDI-DI	Description	EU Class	Rule(s)	EMDN Code	DE Number	Technical Documentation
Продуктови кодове	Основн UDI-DI	Описание	Клас на ЕС	Правило(а)	EMDN код	Номер на нотифициран ия орган	Техническа документация
Kodovi proizvoda	Jedinstvena identifikacija proizvoda (UDI-DI)	Opis	EU klasa	Pravilo/p ravila	EMDN kôd	Broj nadležnog tijela	Tehnička dokumentacija
Produktové kódy	Základní UDI-DI	Popis	Třída EU	Pravidla	Kód EMDN	Číslo notifikovanéh o orgánu	Technická dokumentace
Produktkoder	Grund-læggende UDI-DI	Beskrivelse	EU-klasse	Regel/regler	EMDN-kode	Godkendelses organnummer	Teknisk dokumentation
Product codes	Basis-UDI-DI	Beschrijving	EU-klasse	Regel(s)	EMDN-code	Nummer aangemelde instantie	Technische documentatie
Toote-koodid	Üldine UDI-DI	Kirjeldus	ELi klass	Reegel (Reeglid)	EMDN kood	Teavitatud asutuse number	Tehniline dokumentatsioon
Tuotekoodit	Perus UDI-DI	Kuvaus	EU-luokka	Säännöt	EMDN-koodi	Ilmoitetun laitoksen numero	Tekninen dokumentaatio
Codes produit	UDI-DI de base	Description	Classe UE	Règle(s)	Code EMDN	Numéro de l'organisme notifié	Documentation technique
Produkt-codes	Grund-legende UDI-DI	Beschreibung	EU-Klasse	Vor-schrift (en)	EMDN-Code	Nummer der benannten Stelle	Technische Dokumentation
Κωδικοί προϊόντων	Βασικό UDI-DI	Περιγραφή	Κατηγορία ΕΕ	Κανόνας(ες)	Κωδικός EMDN	Αριθμός κοινοποιημένου οργανισμού (NB)	Τεχνικός φάκελος
Termék-kódok	Alap UDI-DI	Leírás	EU-osztály	Szabály(ok)	EMDN-kód	Bejelentett szerv száma	Műszaki dokumentáció

CONFIDENTIAL AND PROPRIETARY PROPERTY OF VYAIRE MEDICAL

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Codici prodotto	UDI-DI di base	Descrizione	Classe UE	Regole	Codi-ce EMDN	Numero di organismo modificato	Documenta-zione tecnica
Produkta kods	Pamata UDI-DI	Apraksts	ES klase	Noteiku ms(-i)	EMDN kods	Pilnvarotās iestātes numurs	Tehniskā dokumentācija
Gaminių kodai	Pagrīn-dinis UDI priemo-nės identifi-katorius	Aprašas	ES klasė	Taisyk-lė (-ės)	EMDN kodas	NB numeris	Techninė dokumentacija
Kody produk-tów	Podsta-wowe UDI-DI	Opis	Klasa UE	Reguła(-y)	Kod EMDN	Numer jednostki notyfikowanej	Dokumentacja techniczna
Códigos de produto	UDI-DI básica	Descrição	Classe UE	Regra(s)	Código EMDN	Número do organismo notificado	Documentaçã o técnica
Codurile produsului	UDI-DI de bază	Descriere	Clasă UE	Regulam ent(e)	Cod EMDN	Număr organism notificat	Documentație tehnică
Produk-tové kódy	Základ-ný UDI-DI	Opis	Trieda EÚ	Pravidlo (pravidlá)	Kód EMDN	Číslo notifikovanéh o orgánu	Technická dokumentácia
Šifre izdelka	Osnovni UDI-DI	Opis	Razre d EU	Predpis(i)	Šifra EMDN	Številka priglašenege organa	Tehnična dokumentacija
Códigos de producto	UDI-DI básico	Descripción	Clase de UE	Norma(s)	Código de EMDN	Número de organismo notificado	Documentació n técnica
Produktkod er	Grund-läggande UDI-DI	Beskrivning	EU-klass	Regler	EMDN-kod	Nummer anmält organ	Teknisk dokumentatio n

CONFIDENTIAL AND PROPRIETARY PROPERTY OF VYAIRE MEDICAL

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EMDN Code	EMDN Term	Intended Purpose
EMDN код	EMDN срок	Предназначение
EMDN kôd	Pojam prema EMDN-u	Namjena
Kód EMDN	Termín EMDN	Zamýšlený účel
EMDN-kode	EMDN-term	Tilsigtet anvendelse
EMDN-code	EMDN-term	Beoogd doel
EMDN kood	EMDN termin	Kasutuseesmärk
EMDN-koodi	EMDN-termi	Käyttötarkoitus
Code EMDN	Terme EMDN	Usage prévu
EMDN-Code	EMDN-Dauer	Verwendungszweck
Κωδικός EMDN	Όρος EMDN	Προβλεπόμενος σκοπός
EMDN-kód	EMDN-kifejezés	Rendeltetés
Codice EMDN	Termine EMDN	Scopo previsto
EMDN kods	EMDN termíns	Paredzētais mērķis
EMDN kodas	EMDN terminas	Numatyta paskirtis
Kod EMDN	Termin EMDN	Przeznaczenie
Código EMDN	Termo EMDN	Finalidade
Cod EMDN	Termen EMDN	Scop preconizat
Kód EMDN	Pojem EMDN	Zamýšľané použitie
Šifra EMDN	Izraz EMDN	Predvideni namen
Código de EMDN	Término de EMDN	Propósito previsto
EMDN-kod	EMDN-term	Avsedd användning

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 734803 R000

Manufacturer: Vyair Medical, Inc

Address:

26125 N. Riverwoods Blvd
Mettawa
Illinois
60045
USA

Single Registration Number: US-MF-000008254

EU Authorised Representative: Emergo Europe

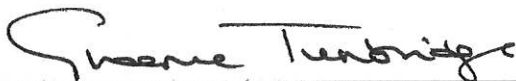
Address:

Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2022-04-22**

Current Issue Date: **2024-05-29**

Starting Validity Date: **2024-05-29**

Expiry Date: **2027-04-21**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 734803 R000

Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12	Intended purpose
Bellavista ventilator BV 1000, 1000e	The Bellavista ventilator was developed for ventilating adult and paediatric patients. Also neonatal patients with a tidal volume ≥ 2 mL. The device is intended for use in clinics and institutional facilities where medically trained professionals are available for attending to the patient. The device can be used at the bedside, as well as for transfer within a facility, when a patient is in need of oxygen.
Bellavista ventilator BV 1000neo	The Bellavista 1000 neo ventilator was developed for ventilating neonatal patients of a tidal volume of ≥ 2 mL. The device is intended for use in clinics and institutional facilities where medically trained professionals are available for attending to the patient. The device can be used at the bedside, as well as for transfer within a facility, when a patient is in need of oxygen.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Flow sensor	Class IIa
SuperNO2VA Et mask & system	Class IIa

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EU Quality Management System Certificate

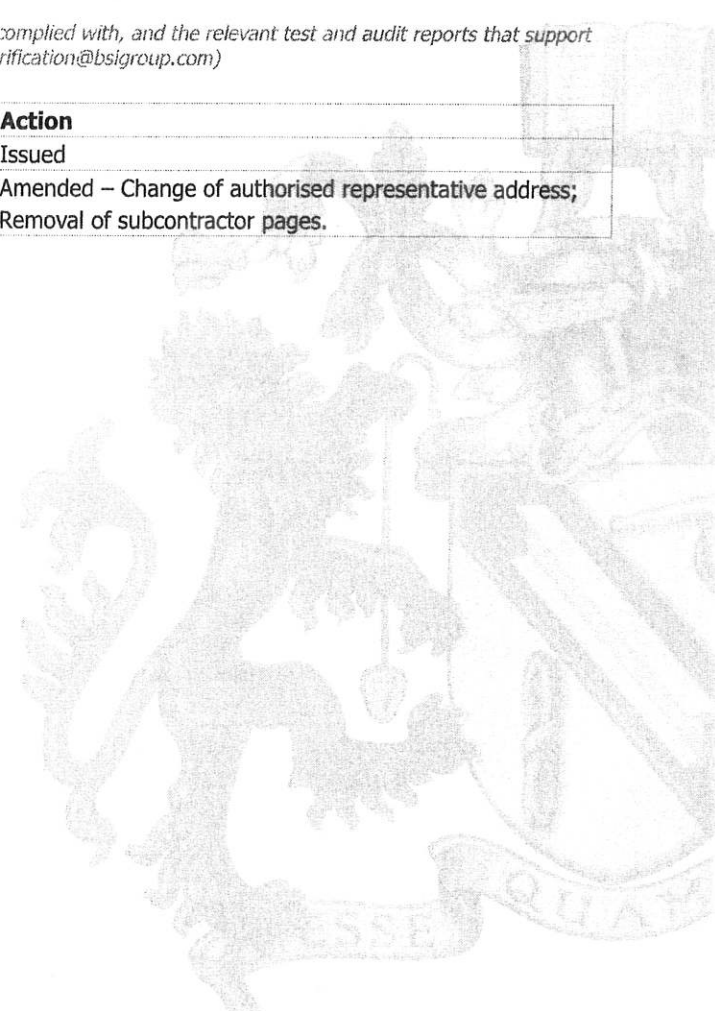
Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 734803 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-04-22	3277241	Issued
Current	30188088	Amended – Change of authorised representative address; Removal of subcontractor pages.



First Issue Date: **2022-04-22**

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