

Declaration of Conformity

issued in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices



PATRON Bohemia a.s.
Ceskolipska 3419, 27601 Melnik, Czech Republic

Medical device name: TOM5-CSI, modular chassis for special seating units for children with special needs
Basic UDI-DI (GMN): 85912460T5YYYYYYYCSI000WL
Manufacture reference: T5YYYYYYYCSI000
Classification (Annex VIII): Class I (non-invasive)
EMDN code: < Y122799 >
Scope of Application: All

Medical device in the means of modular chassis, as a carrier for special seating units for disabled children. Technical aid in the means of the modular stroller chassis, carrier with wheels, for outdoor transport of children with special needs.

Manufacturer declares:

- there has been provided conformity assessment to verify the conformity of above product with the provisions of the Regulation (EU) 2017/74.
- product meets all the appropriate health and safety EU-requirements
- the use of upon mentioned product in usual conditions and in accordance to the information for use and manufacturer advices is safe for the determined kind of use
- there is a bearer of responsibility, that all the manufactured products comply to all the technical documentation and products essential requirements as stated above
- there is implemented and maintained appropriate system to keep series in conformity with this regulation, certified quality management systems: EN ISO 9001, EN ISO 13485
- all the technical documentation is located in the residence of manufacturer
- above-mentioned product complies with following principal standards: EN 12183, EN 12182, ISO 7176, and its consequence regulations.
- other applied standards and regulations: CSN 41 1109, CSN 41 1343, CSN 42 5340, CSN 64 7003, CSN 80 3014, CSN EN 573-3, CSN EN 755-2, PN STAP 44569599-025/80/92

The manufacturer hereby declare under his sole responsibility that the product specified above confirms to the required provisions of the Regulation (EU) 2017/745. Declared in Melnik on 20/05/2021.



PATRON Bohemia a.s.
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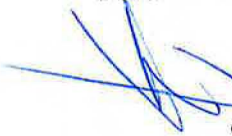

Medical device name: BEN, stroller for children with special needs
Basic UDI-DI (GMN): 85912460B4YYYYYY000000AG
Manufacture reference: B4YYYYYY000000
Classification (Annex VIII): Class I (non-invasive)
EMDN code: < Y122703 >
Scope of Application: All

Medical device in the means of foldable multipurpose stroller for disabled children.
Medical device in the means of the technical aid for transport of children with special needs.

Manufacturer declares:

- there has been provided conformity assessment to verify the conformity of above product with the provisions of the Regulation (EU) 2017/74.
- product meets all the appropriate health and safety EU-requirements
- the use of upon mentioned product in usual conditions and in accordance to the information for use and manufacturer advices is safe for the determined kind of use
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PATRON Bohemia a.s.
Ceskolipska 3419, 27601 Melnik, Czech Republic

Medical device name: CORZINO, stroller for children with special needs
Basic UDI-DI(GMN): 85912460CNYYYYYY000000DM
Manufacture reference: CNYYYYYY000000
Classification (Annex VIII): Class I (non-invasive)
EMDN code: < Y122703 >
Scope of Application: All

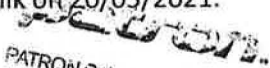
Medical device in the means of foldable multipurpose buggy-stroller for disabled children. Medical device in the means of the technical aid for transport of children with special needs.

Manufacturer declares:

- there has been provided conformity assessment to verify the conformity of above product with the provisions of the Regulation (EU) 2017/74.
- product meets all the appropriate health and safety EU-requirements
- the use of upon mentioned product in usual conditions and in accordance to the information for use and manufacturer advices is safe for the determined kind of use
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PATRON Bohemia a.s.
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Medical device name: CORZO, stroller for children with special needs
Basic UDI-DI (GMN): 85912460CRYYYYYY000000JZ
Manufacture reference: CRYYYYYY000000
Classification (Annex VIII): Class I (non-invasive)
EMDN code: < Y122703 >
Scope of Application: All

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Manufacturer declares:

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PATRON Bohemia a.s.
Ceskolipska 3419, 27601 Melnik, Czech Republic

Medical device name: DENVER, modular chassis for special seating units for children with special needs
Basic UDI-DI (GMN): 85912460RKC151YYY000000GQ
Manufacture reference: RKC151YYY000000
Classification (Annex VIII): Class I (non-invasive)
EMDN code: < Y122799 >
Scope of Application: All

Medical device in the means of modular chassis, as a carrier for special seating units for disabled children. Technical aid in the means of the modular chassis, high-low carrier with wheels, for indoor transport of children with special needs.

Manufacturer declares:

- there has been provided conformity assessment to verify the conformity of above product with the provisions of the Regulation (EU) 2017/74.
- product meets all the appropriate health and safety EU-requirements
- the use of upon mentioned product in usual conditions and in accordance to the information for use and manufacturer advices is safe for the determined kind of use
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PATRON Bohemia a.s.
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Medical device name: DIXIE, stroller for children with special needs
Basic UDI-DI(GMN): 85912460D4YYYYYYY000000DE
Manufacture reference: D4YYYYYYY000000
Classification (Annex VIII): Class I (non-invasive)
EMDN code: < Y122703 >
Scope of Application: All


Medical device in the means of foldable multipurpose stroller for disabled children.
Medical device in the means of the technical aid for transport of children with special needs.

Manufacturer declares:

- there has been provided conformity assessment to verify the conformity of above product with the provisions of the Regulation (EU) 2017/74.
- product meets all the appropriate health and safety EU-requirements
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PATRON Bohemia a.s.
Ceskolipska 3419, 27601 Melnik, Czech Republic

Medical device name: DURANGO, modular chassis for special seating units for children with special needs
Basic UDI-DI (GMN): 85912460RKC161YYY000000HP
Manufacture reference: RKC161YYY000000
Classification (Annex VIII): Class I (non-invasive)
EMDN code: < Y122799 >
Scope of Application: All

Medical device in the means of modular chassis, as a carrier for special seating units for disabled children. Technical aid in the means of the modular chassis, high-low carrier with wheels, for outdoor transport of children with special needs.


Manufacturer declares:

- there has been provided conformity assessment to verify the conformity of above product with the provisions of the Regulation (EU) 2017/74.
- product meets all the appropriate health and safety EU-requirements
- the use of upon mentioned product in usual conditions and in accordance to the information for use and manufacturer advices is safe for the determined kind of use
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PATRON Bohemia a.s.
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Medical device name: FROGGO, postural seating system for children with special needs
Basic UDI-DI(GMN): 85912460FRYYYYYYY000000PE
Manufacture reference: FRYYYYYYYY000000
Classification (Annex VIII): Class I (non-invasive)
EMDN code: < Y180939 >
Scope of Application: All

Medical device in the means of modular seating system for disabled children. Technical aid in the means of postural support device for fully controlled seating and positioning of children with special needs.

Manufacturer declares:

- there has been provided conformity assessment to verify the conformity of above product with the provisions of the Regulation (EU) 2017/74.
- product meets all the appropriate health and safety EU-requirements
- the use of upon mentioned product in usual conditions and in accordance to the information for use and manufacturer advices is safe for the determined kind of use
- there is a bearer of responsibility, that all the manufactured products comply to all the technical documentation and products essential requirements as stated above
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- all the technical documentation is located in the residence of manufacturer
- above-mentioned product complies with following principal standards: ISO 16840, ISO 7176, EN 12183, EN 12182, and its consequence regulations.
- other applied standards and regulations: CSN 41 1109, CSN 41 1343, CSN 42 5340, CSN 64 7003, CSN 80 3014, CSN EN 573-3, CSN EN 755-2, , PN STAP 44569599-025/80/92

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PATRON Bohemia a.s.
Ceskolipska 3419, 27601 Melnik, Czech Republic


Medical device name: JACKO, stroller for children with special needs
Basic UDI-DI(GMN): 85912460J5YYYYYYY000000PK
Manufacture reference: J5YYYYYYY000000
Classification (Annex VIII): Class I (non-invasive)
EMDN code: < Y122703 >
Scope of Application: All

Medical device in the means of foldable multipurpose stroller for disabled children.
Medical device in the means of the technical aid for transport of children with special needs.

Manufacturer declares:

- there has been provided conformity assessment to verify the conformity of above product with the provisions of the Regulation (EU) 2017/74.
- product meets all the appropriate health and safety EU-requirements
- the use of upon mentioned product in usual conditions and in accordance to the information for use and manufacturer advices is safe for the determined kind of use
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- other applied standards and regulations: CSN 41 1109, CSN 41 1343, CSN 42 5340, CSN 64 7003, CSN 80 3014, CSN EN 573-3, CSN EN 755-2, , PN STAP 44569599-025/80/92

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PATRON Bohemia a.s.
Ceskolipska 3419, 27601 Melnik, Czech Republic

Medical device name: PIPER, stroller for children with special needs
Basic UDI-DI (GMN): 85912460PIYYYYYYY000000RZ
Manufacture reference: PIYYYYYYY000000
Classification (Annex VIII): Class I (non-invasive)
EMDN code: < Y122703 >
Scope of Application: All

Medical device in the means of foldable multipurpose buggy-stroller for disabled children. Medical device in the means of the technical aid for transport of children with special needs.

Manufacturer declares:

- there has been provided conformity assessment to verify the conformity of above product with the provisions of the Regulation (EU) 2017/74.
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PATRON Bohemia a.s.
Českolipska 3419, 27601 Melnik, Czech Republic


Medical device name: TAMPA, postural seating system for children with special needs
Basic UDI-DI(GMN): 85912460TMYYYYYY0000005C
Manufacture reference: TMYYYYYY000000
Classification (Annex VIII): Class I (non-invasive)
EMDN code: < Y180939 >
Scope of Application: All

Medical device in the means of modular seating system for disabled children. Technical aid in the means of postural support device for fully controlled seating and positioning of children with special needs.

Manufacturer declares:

- there has been provided conformity assessment to verify the conformity of above product with the provisions of the Regulation (EU) 2017/74.
- product meets all the appropriate health and safety EU-requirements
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PATRON Bohemia a.s.
Ceskolipska 3419, 27601 Melnik, Czech Republic

Medical device name: TOM 4, stroller for children with special needs
Basic UDI-DI(GMN): 85912460T4YYYYYY0000004Z
Manufacture reference: T4YYYYYY000000
Classification (Annex VIII): Class I (non-invasive)
EMDN code: < Y122703 >
Scope of Application: All


Medical device in the means of foldable multipurpose stroller for disabled children.
Medical device in the means of the technical aid for transport of children with special needs.

Manufacturer declares:

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Medical device name: TOM4-CSI, modular chassis for special seating units for children with special needs
Basic UDI-DI (GMN): 85912460T4YYYYYYYCSI000V9
Manufacture reference: T4YYYYYYYCSI000
Classification (Annex VIII): Class I (non-invasive)
EMDN code: < Y122799 >
Scope of Application: All

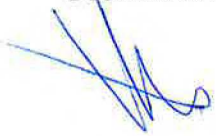
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PATRON Bohemia a.s.
Ceskolipska 3419, 27601 Melnik, Czech Republic

Medical device name: TOM 5, stroller for children with special needs
Basic UDI-DI (GMN): 85912460T5YYYYYY0000006C
Manufacture reference: T5YYYYYY000000
Classification (Annex VIII): Class I (non-invasive)
EMDN code: < Y122703 >
Scope of Application: All

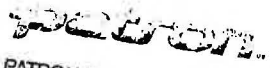
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Medical device in the means of the technical aid for transport of children with special needs.

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- all the technical documentation is located in the residence of manufacturer
- above-mentioned product complies with following principal standards: EN 12183, EN 12182, ISO 7176 and its consequence regulations.
- other applied standards and regulations: CSN 41 1109, CSN 41 1343, CSN 42 5340, CSN 64 7003, CSN 80 3014, CSN EN 573-3, CSN EN 755-2, , PN STAP 44569599-025/80/92

The manufacturer hereby declare under his sole responsibility that the product specified above confirms to the required provisions of the Regulation (EU) 2017/745.
Declared in Melnik on 20/05/2021.


Ing. Jiri Kotik
R&D Executive Manager


PATRON Bohemia a.s.
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tel.: +420 315 630 111, fax: +420 315 630 100
IČ: 61676314, DIČ: CZ61676314

3



Nome Fabbricante: ORMESA s.r.l.
Manufacturer's Name:

Indirizzo Fabbricante: Via A. Da Sangallo, 1 | 06034 Foligno (PG) – ITALY
Manufacturer's Address:

Certificazioni Fabbricante UNI EN ISO 13485:2016
(Manufacturer Certifications) Dispositivi medici – Sistemi di gestione per la qualità. Requisiti per scopi regolamentari
Medical devices – Quality management systems. Requirements for regulatory purposes

SRN Non ancora disponibile
(Numero di Registrazione Unico): *Not yet available*
(Single Registration Number):

ORMESA srl dichiara sulla sua responsabilità che il Dispositivo Medico*Ormesa srl declares on its own responsibility that the Medical Device*

UDI-DI di base **805571570BUGL9**
Basic UDI-DI:

Nome del Dispositivo: **BUG**
Name of the Device:

Codice DEL Dispositivo: Vedi Allegato 1 da pagina 3 a pagina 7
Product code: *See Attachment from page 3 to page 7*

Destinazione d'uso: BUG è una unità di seduta posturale indicata per bambini con disabilità (Paralisi Cerebrali Infantili, patologie degenerative con menomazioni funzionali, patologie sindromiche con menomazioni funzionali) facilmente adattabile grazie alla sua modularità. Indicato per utenti che abbiano scarso o nullo controllo del tronco e del capo e che necessitino di un appropriata stabilizzazione a livello pelvico per poter assumere, nelle situazioni in cui la funzionalità residua lo permetta, la postura più appropriata nei diversi contesti quotidiani, in ambito esterno ed interno. L'uso di BUG e dei suoi accessori presuppone sempre la prescrizione di un medico specialista che ne verifichi anche l'impiego.
Intended purpose: *BUG is a postural sitting unit indicated for children with disabilities (Infantile Cerebral Palsy, degenerative pathologies with functional impairments, syndromic pathologies with impairments functional) easily adaptable thanks to its modularity. Suitable for users who have little or no control of the trunk and head and needing appropriate stabilization a pelvic level to be able to assume, in situations where residual functionality allows it, the more appropriate posture in different everyday contexts, both internally and externally. The use of BUG and its accessories always requires the prescription of a specialist doctor who also check its use.*

Classificazione di Rischio: Classe: / Class: I
Risk Classification:

soddisfa le prescrizioni del Regolamento (UE) MDR 2017/745 relativo ai i dispositivi medici*Is compliant with the requirements of the Regulation (EU) 2017/745 on medical devices.*

Specifiche comuni utilizzate: Nessuna
Common Specification applied: *None*

Norme Armonizzate e norme tecniche utilizzate Vedi Allegato 2 da pagina 7 a pagina 7
Harmonized and Technical Standards applied *See Attachment from page 7 to page 7*

Valutazione della Conformità: Dichiarazione di Conformità "UE" in accordo con Allegato II & III del Regolamento (UE) 2017/745
Conformity Assessment Route: *EU conformity declaration according to Annex II & III of the Regulation (EU) 2017/745*

Foligno, 26/5/2021

Firma / *Signature:* Chiara Menichini (Legale Rappresentante)


Allegato 1

Codici identificativi Configurazioni e Componenti (Configurations and Components ID code List)

UDI DI	Codice art. Item Code	Modello Model
08055715702864	106829	869 BASE DA ESTERNO 4 RUOTE, TELAIO NERO, SMALL 869 OUTDOOR four wheels base, Small
08055715702871	106830	869 BASE DA ESTERNO 4 RUOTE, TELAIO NERO, MEDIUM 869 OUTDOOR four wheels base, Medium
08055715702888	108117	856 BASE DA INTERNO ELEVABILE, SMALL 856 Indoor high-low feeding base, Small
08055715702895	108118	856 BASE DA INTERNO ELEVABILE, MEDIUM 856 Indoor high-low feeding base, Medium
08055715702901	108121	850 BASE DA INTERNO FISSA, SMALL 850 Indoor compact floor base, Small
08055715702918	108122	850 BASE DA INTERNO FISSA, MEDIUM 850 Indoor compact floor base, Medium
08055715702925	108119	851 BASE DA INTERNO COMPATTA ELEVABILE SMALL 851 Indoor high-low compact base, Small
08055715702932	108120	851 BASE DA INTERNO COMPATTA ELEVABILE MEDIUM 851 Indoor high-low compact base, Medium
08055715702949	106821	BUG SMALL 869 NARROW BASE (black), LIGHT GREY GREEN/BLUE
08055715702956	106822	BUG SMALL 869 NARROW BASE (black), DARK GREY GREEN/BLUE
08055715702963	106823	BUG SMALL 869 NARROW BASE (black), LIGHT GREY PINK/BLUE
08055715702970	106824	BUG SMALL 869 NARROW BASE (black), DARK GREY PINK/BLUE
08055715702987	106857	BUG SMALL 869 NARROW BASE (black) LIGHT GREY GREEN
08055715702994	106858	BUG SMALL 869 NARROW BASE (black) LIGHT GREY PINK
08055715703007	106859	BUG SMALL 869 NARROW BASE (black) DARK GREY GREEN
08055715703014	106860	BUG SMALL 869 NARROW BASE (black) DARK GREY PINK
08055715703021	106825	BUG MEDIUM 869 NARROW BASE (black), LIGHT GREY GREEN/BLUE
08055715703038	106826	BUG MEDIUM 869 NARROW BASE (black), DARK GREY GREEN/BLUE
08055715703045	106827	BUG MEDIUM 869 NARROW BASE (black), LIGHT GREY PINK/BLUE
08055715703052	106828	BUG MEDIUM 869 NARROW BASE (black), DARK GREY PINK/BLUE
08055715703069	106914	BUG MEDIUM 869 NARROW BASE (black) LIGHT GREY GREEN
08055715703076	106915	BUG MEDIUM 869 NARROW BASE (black) LIGHT GREY PINK
08055715703083	106916	BUG MEDIUM 869 NARROW BASE (black) DARK GREY GREEN
08055715703090	106917	BUG MEDIUM 869 NARROW BASE (black) DARK GREY PINK
08055715703106	106813	BUG SMALL 856 HIGH LOW WORKING CHAIR, LIGHT GREY GREEN/BLUE
08055715703113	106814	BUG SMALL 856 HIGH LOW WORKING CHAIR, DARK GREY GREEN/BLUE
08055715703120	106815	BUG SMALL 856 HIGH LOW WORKING CHAIR, LIGHT GREY PINK/BLUE
08055715703137	106816	BUG SMALL 856 HIGH LOW WORKING CHAIR, DARK GREY PINK/BLUE
08055715703144	106853	BUG SMALL 856 HIGH LOW WORKING CHAIR, LIGHT GREY GREEN
08055715703151	106854	BUG SMALL 856 HIGH LOW WORKING CHAIR, LIGHT GREY PINK
08055715703168	106855	BUG SMALL 856 HIGH LOW WORKING CHAIR, DARK GREY GREEN
08055715703175	106856	BUG SMALL 856 HIGH LOW WORKING CHAIR, DARK GREY PINK
08055715703182	106817	BUG MEDIUM 856 HIGH LOW WORKING CHAIR, LIGHT GREY GREEN/BLUE
08055715703199	106818	BUG MEDIUM 856 HIGH LOW WORKING CHAIR, DARK GREY GREEN/BLUE
08055715703205	106819	BUG MEDIUM 856 HIGH LOW WORKING CHAIR, LIGHT GREY PINK/BLUE
08055715703212	106820	BUG MEDIUM 856 HIGH LOW WORKING CHAIR, DARK GREY PINK/BLUE
08055715703229	106910	BUG MEDIUM 856 HIGH LOW WORKING CHAIR, LIGHT GREY GREEN
08055715703236	106911	BUG MEDIUM 856 HIGH LOW WORKING CHAIR, LIGHT GREY PINK
08055715703243	106912	BUG MEDIUM 856 HIGH LOW WORKING CHAIR, DARK GREY GREEN
08055715703250	106913	BUG MEDIUM 856 HIGH LOW WORKING CHAIR, DARK GREY PINK
08055715703267	106797	BUG SMALL 850 FLOOR BASE, LIGHT GREY GREEN/BLUE

08055715703274	106798	BUG SMALL 850 FLOOR BASE, DARK GREY GREEN/BLUE
08055715703281	106799	BUG SMALL 850 FLOOR BASE, LIGHT GREY PINK/BLUE
08055715703298	106800	BUG SMALL 850 FLOOR BASE, DARK GREY PINK/BLUE
08055715703304	106845	BUG SMALL 850 FLOOR BASE, LIGHT GREY GREEN
08055715703311	106846	BUG SMALL 850 FLOOR BASE, LIGHT GREY PINK
08055715703328	106847	BUG SMALL 850 FLOOR BASE, DARK GREY GREEN
08055715703335	106848	BUG SMALL 850 FLOOR BASE, DARK GREY PINK
08055715703342	106801	BUG MEDIUM 850 FLOOR BASE, LIGHT GREY GREEN/BLUE
08055715703359	106802	BUG MEDIUM 850 FLOOR BASE, DARK GREY GREEN/BLUE
08055715703366	106803	BUG MEDIUM 850 FLOOR BASE, LIGHT GREY PINK/BLUE
08055715703373	106804	BUG MEDIUM 850 FLOOR BASE, DARK GREY PINK/BLUE
08055715703380	106902	BUG MEDIUM 850 FLOOR BASE, LIGHT GREY GREEN
08055715703397	106903	BUG MEDIUM 850 FLOOR BASE, LIGHT GREY PINK
08055715703403	106904	BUG MEDIUM 850 FLOOR BASE, DARK GREY GREEN
08055715703410	106905	BUG MEDIUM 850 FLOOR BASE, DARK GREY PINK
08055715703427	106805	BUG SMALL 851 HIGH-LOW COMPACT BASE, LIGHT GREY GREEN/BLUE
08055715703434	106806	BUG SMALL 851 HIGH-LOW COMPACT BASE, DARK GREY GREEN/BLUE
08055715703441	106807	BUG SMALL 851 HIGH-LOW COMPACT BASE, LIGHT GREY PINK/BLUE
08055715703458	106808	BUG SMALL 851 HIGH-LOW COMPACT BASE, DARK GREY PINK/BLUE
08055715703465	106849	BUG SMALL 851 HIGH-LOW COMPACT BASE, LIGHT GREY GREEN
08055715703472	106850	BUG SMALL 851 HIGH-LOW COMPACT BASE, LIGHT GREY PINK
08055715703489	106851	BUG SMALL 851 HIGH-LOW COMPACT BASE, DARK GREY GREEN
08055715703496	106852	BUG SMALL 851 HIGH-LOW COMPACT BASE, DARK GREY PINK
08055715703502	106809	BUG MEDIUM 851 HIGH-LOW COMPACT BASE, LIGHT GREY GREEN/BLUE
08055715703519	106810	BUG MEDIUM 851 HIGH-LOW COMPACT BASE, DARK GREY GREEN/BLUE
08055715703526	106811	BUG MEDIUM 851 HIGH-LOW COMPACT BASE, LIGHT GREY PINK/BLUE
08055715703533	106812	BUG MEDIUM 851 HIGH-LOW COMPACT BASE, DARK GREY PINK/BLUE
08055715703540	106906	BUG MEDIUM 851 HIGH-LOW COMPACT BASE, LIGHT GREY GREEN
08055715703557	106907	BUG MEDIUM 851 HIGH-LOW COMPACT BASE, LIGHT GREY PINK
08055715703564	106908	BUG MEDIUM 851 HIGH-LOW COMPACT BASE, DARK GREY GREEN
08055715703571	106909	BUG MEDIUM 851 HIGH-LOW COMPACT BASE, DARK GREY PINK
08055715703588	107004	863 POGGIATESTA REGOLABILE con protezioni occipito-parietali, SMALL <i>863 Multiadjustable Headrest with parietal supports, Small</i>
08055715703595	107005	863 POGGIATESTA REGOLABILE con protezioni occipito-parietali, MEDIUM <i>863 Multiadjustable Headrest with parietal supports, Medium</i>
08055715703601	106898	852 POGGIATESTA con protezioni parietali regolabili, SMALL <i>852 Headrest with parietal supports, Small</i>
08055715703618	106899	852 POGGIATESTA con protezioni parietali regolabili, MEDIUM <i>852 Headrest with parietal supports, Medium</i>
08055715703625	106690	942 POGGIATESTA ERGONOMICO REGOLABILE con alette, misura SMALL <i>942 Ergonomic headrest Small</i>
08055715703632	107293	942 POGGIATESTA ERGONOMICO REGOLABILE con alette, misura MEDIUM per BUG SMALL <i>942 Ergonomic headrest for Bug Small</i>
08055715703649	106691	942 POGGIATESTA ERGONOMICO REGOLABILE con alette, misura MEDIUM <i>942 Ergonomic headrest Medium</i>
08055715703656	106692	942 POGGIATESTA ERGONOMICO REGOLABILE con alette, misura LARGE per BUG MEDIUM <i>942 Ergonomic headrest for Bug Medium</i>
08055715703663	105174	835 POGGIATESTA SAGOMATO, SMALL <i>835 Shaped headrest, Small</i>
08055715703670	105175	835 POGGIATESTA SAGOMATO, MEDIUM <i>835 Shaped headrest, Medium</i>
08055715703687	106651	934 ATTACO PER POGGIATESTA A SOSPENSIONE <i>934 Suspension headrest attachment. Only available for 863 headrest</i>
08055715703694	106617	838 PELOTTE TORACALI REGOLABILI, SMALL <i>838 Adjustable lateral Supports, Small</i>
08055715703700	106618	838 PELOTTE TORACALI REGOLABILI, MEDIUM

		<i>838 Adjustable lateral Supports, Medium</i>
08055715703717	108109	868 PELOTTE FRONTALI con snodo, SMALL <i>868 Adjustable wrappable and flexible trunk supports, Small</i>
08055715703724	108110	868 PELOTTE FRONTALI con snodo (avvolgente), MEDIUM <i>868 Adjustable wrappable and flexible trunk supports, Medium</i>
08055715703731	107756	834 DIVARICATORE imbottito e regolabile, SMALL <i>834 Padded abduction block, Small</i>
08055715703748	107757	834 DIVARICATORE imbottito e regolabile, MEDIUM <i>834 Padded abduction block, Medium</i>
08055715703755	105176	834R DIVARICATORE imbottito regolabile in profondità e abduzione, SMALL <i>834R Adjustable padded abduction block, Small</i>
08055715703762	105177	834R DIVARICATORE imbottito regolabile in profondità e abduzione, MEDIUM <i>834R Adjustable padded abduction block, Medium</i>
08055715703779	106611	853 CINGHIA A BRETTELLAGGIO, SMALL <i>853 Vest harness, Small</i>
08055715703786	106612	853 CINGHIA A BRETTELLAGGIO, MEDIUM <i>853 Vest harness, Medium</i>
08055715703793	108111	903 CINGHIA A BRETTELLAGGIO A CINQUE PUNTI, SMALL <i>903 Five point vest Harness, Small</i>
08055715703809	108112	903 CINGHIA A BRETTELLAGGIO A CINQUE PUNTI, MEDIUM <i>903 Five point vest Harness, Medium</i>
08055715703816	107770	906 CINTURA A BRETTELLAGGIO A CINQUE PUNTI, SMALL <i>906 Five point harness, Small</i>
08055715703823	107771	906 CINTURA A BRETTELLAGGIO A CINQUE PUNTI, MEDIUM <i>906 Five point harness, Medium</i>
08055715703830	102794	920 CINTURA A QUATTRO PUNTI, SMALL <i>920 4 Point belt, Small</i>
08055715703847	102795	920 CINTURA A QUATTRO PUNTI, MEDIUM <i>920 4 Point belt, Small</i>
08055715703854	107752	827 CINTURINI FERMAPIEDI, SMALL <i>827 Foot straps</i>
08055715703861	108123	839 APPOGGIAMANI ANTERIORE, SMALL <i>839 Adjustable front handle, Small</i>
08055715703878	108124	839 APPOGGIAMANI ANTERIORE, MEDIUM <i>839 Adjustable front handle, Medium</i>
08055715703885	106773	824 TAVOLO con INCAVO regolabile in altezza ed inclinazione, SMALL <i>824 Adjustable transparent tray, Small</i>
08055715703892	106774	824 TAVOLO con INCAVO regolabile in altezza ed inclinazione, MEDIUM <i>824 Adjustable transparent tray, Medium</i>
08055715703908	107301	824B-S TAV.GRIGIO X BASI DA INT.BUG <i>824B Wide tray just for 850- 851 -856 indoor Bases, Small</i>
08055715703915	107302	824B-M TAV.GRIGIO X BASI DA INT.BUG <i>824B Wide tray just for 850- 851 -856 indoor Bases, Medium</i>
08055715703922	102940	905 FRENO MANUALE per BUG (solo per base da esterno 869), SMALL <i>905 Hand brake for 869 base, Small</i>
08055715703939	102941	905 FRENO MANUALE per BUG (solo per base da esterno 869), MEDIUM <i>905 Hand brake for 869 base, Medium</i>
08055715703946	102982	935 CESTINO PORTABOMBOLA (solo per base da esterno 869), SMALL <i>935 Oxygen bottle Holder, Small</i>
08055715703953	102983	935 CESTINO PORTABOMBOLA (solo per base da esterno 869), MEDIUM <i>935 Oxygen bottle Holder, Medium</i>
08055715703960	106619	911 PORTARESPIRATORE per BUG (solo per base da esterno 869), SMALL <i>911 Vent tray, Small</i>
08055715703977	106891	911 PORTARESPIRATORE per BUG (solo per base da esterno 869), MEDIUM <i>911 Vent tray, Medium</i>
08055715703984	108129	819 CAPPOTTINA con BORDO ROSA, SMALL <i>819 Canopy black/pink, Small</i>

 <small>MADE IN ITALY SINCE 1980</small>	DICHIARAZIONE DI CONFORMITÀ "UE" PER DISPOSITIVI MEDICI <i>EU DECLARATION OF CONFORMITY</i> <i>FOR MEDICAL DEVICES</i>	Rev. 1
		Date 26/5/2021


08055715703991	108128	819 CAPPOTTINA con BORDO VERDE, SMALL <i>819 Canopy black/green, Small</i>
08055715704004	108131	819 CAPPOTTINA con BORDO ROSA, MEDIUM <i>819 Canopy black/pink, Medium</i>
08055715704011	108130	819 CAPPOTTINA con BORDO VERDE, MEDIUM <i>819 Canopy black/green, Medium</i>
08055715704028	108113	825 SACCA PARAPIOGGIA, SMALL <i>825 Rain cover, Small</i>
08055715704035	108114	825 SACCA PARAPIOGGIA, MEDIUM <i>825 Rain cover, Medium</i>
08055715704042	106621	818 SACCA TERMICA, SMALL <i>818 Thermal cover, Small</i>
08055715704059	106622	818 SACCA TERMICA, MEDIUM <i>818 Thermal cover, Medium</i>
08055715704066	102796	892 TAPPEZZERIA IMBOTTITA per PEDANA, SMALL <i>892 Padded covering for footrest, Small</i>
08055715704073	102797	892 TAPPEZZERIA IMBOTTITA per PEDANA, MEDIUM <i>892 Padded covering for footrest, Medium</i>
08055715704080	106925	854 OMBRELLINO PARASOLE, GRIGIO CHIARO con BORDO ROSA <i>854 Parasol, light grey/pink</i>
08055715704097	106924	854 OMBRELLINO PARASOLE, GRIGIO CHIARO con BORDO VERDE <i>854 Parasol, light grey/green</i>
08055715704103	106927	854 OMBRELLINO PARASOLE, GRIGIO SCURO con BORDO ROSA <i>854 Parasol, dark grey/pink</i>
08055715704110	106926	854 OMBRELLINO PARASOLE, GRIGIO SCURO con BORDO VERDE <i>854 Parasol, dark grey/green</i>
08055715704127	102681	858 CESTINO in rete per BUG (solo per base da esterno 869), SMALL <i>858 Net basket for 869 Base, Small</i>
08055715704134	102682	858 CESTINO in rete per BUG (solo per base da esterno 869), MEDIUM <i>858 Net basket for 869 Base, Medium</i>
08055715704141	102801	922 PORTABOTTIGLIA (solo per base da esterno 869) <i>922 Bottle holder for 869 base</i>
08055715704158	102612	891 ANCORAGGI ISO 7176-19 (4 anelli) per cinture a 4 punte di ancoraggio base 869 al veicolo <i>891 Set of 4 tie down hooks for the forward-facing transport of the pushchair in a motor vehicle</i>
08055715704165	107772	894 CINTURA PELVICA A 45° <i>894 45° pelvic belt</i>

Allegato 2

Norme Armonizzate e Norme Tecniche utilizzate

Harmonized and Technical Standards applied

UNI CEI EN ISO 14971	Dispositivi medici - Applicazione della gestione dei rischi ai dispositivi medici <i>Medical Devices - Application of risk management to medical device</i>
UNI EN 12182	Ausili tecnici per persone disabili - requisiti generali e metodi di prova <i>Technical aids for disabled persons - general requirements and test methods</i>
ISO 9999	Ausili tecnici per persone disabili - Classificazione <i>Technical aids for persons with disabilities - Classification and terminology</i>
UNI EN 1041	Informazioni fornite dal fabbricante con i dispositivi medici <i>Information supplied by the manufacture with medical devices</i>
UNI CEI EN ISO 15223-1	Dispositivi medici - Simboli da utilizzare nelle etichette del dispositivo medico, nell'etichettatura e nelle informazioni che devono essere fornite - Parte 1: Requisiti generali

	DICHIARAZIONE DI CONFORMITÀ “UE” PER DISPOSITIVI MEDICI <i>EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES</i>	Rev. 1 Date 26/5/2021
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	<i>Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements</i>
UNI EN 12183	Prodotti destinati all'assistenza di persone con disabilità – Requisiti generali e metodi di prova <i>Manual Wheelchairs - Requirements And Test Methods EN 12182:2012 Technical aids for disabled persons – general requirements and test methods</i>
ISO 7176-1	Sedie a rotelle – parte 1. determinazione della stabilità statica <i>Wheelchairs - part 1: determination of static stability</i>
ISO 7176-3	Sedie a rotelle – parte 3. determinazione della efficacia dei freni <i>Wheelchairs - Part 3: Determination of effectiveness of brakes</i>
ISO 7176-5	Sedie a rotelle – parte 5. determinazione delle dimensioni complessive, massa e ingombro di sterzata <i>Wheelchairs - part 5: determination of overall dimensions, mass and turning space</i>
ISO 7176-7	Sedie a rotelle – parte 7. determinazione delle misurazioni di seduta e delle dimensioni delle ruote <i>Wheelchairs- part 7: measurement of seating and wheel dimensions</i>
ISO 7176-8	Sedie a rotelle – parte 8. requisiti e metodi di prova per la resistenza statica, di impatto e fatica <i>Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths</i>
ISO 7176-11	Sedie a rotelle – parte 11. manichini di prova <i>Wheelchairs - part 11: test dummies</i>
ISO 7176-15	Sedie a rotelle – parte 15. requisiti per la diffusione delle informazioni, per la documentazione e la etichettatura <i>Wheelchairs - part 15: requirements ofr information disclosure, documentation and labelling</i>
ISO 7176-19	Sedie a rotelle – parte 19. Dispositivi per la mobilità con ruote da usare in motoveicoli <i>Wheelchairs - part 19: wheeled mobility devices for use as seats in motor vehicles</i>
ISO 7176-22	Sedie a rotelle – parte 22. Procedure <i>Wheelchairs - part 22: set-up procedures</i>



PO Box 4209 • Palos Verdes, CA 90274 • USA
 888-CONVAID • 310/ 618-0111
 International@convaid.com www.convaid.com

APPENDIX A

DECLARATION OF CONFORMITY

Application of Council Directive: Medical Device Directive 93/42 EEC

Conformity declared to Standard: Essential Requirements of MDD 93/42, ISO 7176, EN12182, EN12183, ISO 10993-1 and ISO 14971-2007

Manufacturer: Convaid Products, Inc.

Manufacturer's Address: P.O. Box 4209, Palos Verdes, CA 90274, USA

Authorized Representative: BS Partnership
41 Dan y Coed Road
Cardiff, CF23 6NB, UK

Tilt in Space Folding Dependent Wheelchair Model name: Scout

Model Number and 90xxxx Sales Order No.:

SC112 (900492), SC12 (902493), SC112T (900498), SC12T (902494), SC12E (902897), SC12TE (902901)
 SC114 (902518), SC14 (902519), SC114T (902516), SC14T (902520), SC14E (902898), SC14TE (902902)
 SC116 (902544), SC16 (902545), SC116T (902517), SC16T (902546), SC16E (902899), SC16TE (902903)
 SC118 (902569), SC18 (902570), SC118T (902434), SC18T (902571), SC18E (902900), SC18TE (902904)

The numerical portion of the model number denotes seat width, in inches). The transit models are identified by a "T" in the model number. Models numbers containing "T" are sold without seating fabric. (9xxxxxx) denote sales order numbers.

The undersigned declares the above named equipment conforms to the above Standards and Directive

Name: Donald Griggs

Company: Convaid Products, Inc.

Position: Quality Assurance Manager

Signature: Donald Griggs Date: 1-12-11

Authorized Representative:

Name: Jonathan Phillips

Signature: Phillips Date: 13/01/11



EU Declaration of Conformity

Manufacturer

Name R82 A/S
Address of registered place of business Parallelvej 3
8751 Gedved
Denmark
SRN N/A

This EU declaration of conformity is issued under the sole responsibility of the manufacturer

Basic UDI-DI N/A

Product / device

Name Stingray frame
Size 1, 2 and all accessories
Intended purpose Buggy frame for disabled children

Risk class of the device Class 1

The device covered by present declaration is in conformity with EU Regulation 2017/745 on medical devices and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity

Reference to Common Specifications used and in relation to which conformity is declared

Standard	EN 12182:2012	Assistive products for persons with disability General requirements and test methods
	EN 12183:2009	Manual wheelchairs Requirements and test methods

Place Gedved
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