Doc Title:	Rythmic™ Ultima_Declaration Of Conformity MDD						
Doc #:	ML-PR-15026	Rev.:	5	Page:	1 of 3	Status:	Released

Type:	Declaration Of Conformity			Unclassified Uncontrolled when printed or copied!
Created by:	Christos Freris	Ownership:	Regulatory Affairs	
Eff. Date:	May 31, 2024	Origin: Internal	Owner: Achilleas Tsoukalis	

Item Name	Rythmic™ Ultima Model				
Item Code:	15000	Item Version:	1	Item ERP No.: NA	Item Level: Model

Governance	Doc #:	Title	Revision	Released
Used Form	ML-TMP-00001	NA	NA	Jul 5, 2018
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1 Document Approval - Electronic Signatures

Natalia Ghikas;Document Control Review;Dec 23, 2022 12:17 PM EET
Christos Freris;Final Approval;May 28, 2024 4:35 PM EEST
Sasa Karpeti;Final Approval;May 29, 2024 3:18 PM EEST
Achilleas Tsoukalis;Final Approval;May 31, 2024 2:16 PM EEST

2 Declaration of Conformity

We,

the medical device manufacturer,

Micrel Medical Devices S.A.
42 Konstantinoupoleos Str.
Koropi/Athens GR-19441
GREECE

declare under our sole responsibility that the products listed in the ANNEX of this document are

- in conformity with the essential requirements and principles for safety and performance of the

MDD: Medical Devices Directive 93/42/EEC
amended by Council Directive 2007/47/EC

- classified Class IIb according to the Annex IX, rule 11 of the MDD
- CE certified according to the conformity assessment route Full Quality Assurance System as outlined in Annex II (excluding section 4) of the MDD

under the supervision of the

Notified Body SGS Belgium NV (CE1639), SGS House, Noorderlaan 87, 2030 Antwerp, Belgium

This declaration is signed electronically and valid until 2024-05-24, which is the expiry date of the EC Certificate BG19/871877.

Name and Function	Place and Date of issue	Signature

3 ANNEX

3.1 Model

Pos.	Basic UDI-DI	Technical File ID	Device Model Name
1	5206116150003D	TF-15	Rythmic Ultima

3.2 Product Sales Packs and Variants

Sales Pack…			…contains Variant	
Pos.	Item Code	Item Name	Item Code	Item Name Picture
1	15101	Rythmic™ ULTIMA XS (Yellow)	15001	Rythmic™ SERENA XS (Green)
2	15102	Rythmic™ ULTIMA XS (Yellow) Cellular	15002	Rythmic™ SERENA XS (Green) Cellular
3	15103	Rythmic™ ULTIMA XS (Blue)	15003	Rythmic™ SERENA S (Green)
4	15104	Rythmic™ ULTIMA XS (Blue) Cellular	15004	Rythmic™ SERENA S (Green) Cellular
5	15105	Rythmic™ ULTIMA S (Yellow)	15005	Rythmic™ SERENA XS (Magenta)
6	15106	Rythmic™ ULTIMA S (Yellow) Cellular	15006	Rythmic™ SERENA XS (Magenta) Cellular
7	15107	Rythmic™ ULTIMA S (Blue)	15007	Rythmic™ SERENA S (Magenta)
8	15108	Rythmic™ ULTIMA S (Blue) Cellular	15008	Rythmic™ SERENA S (Magenta) Cellular
9	15109	Rythmic™ ULTIMA XL (Yellow)	15009	Rythmic™ ULTIMA XL (Yellow)
10	15110	Rythmic™ ULTIMA XL (Yellow) Cellular	15010	Rythmic™ ULTIMA XL (Yellow) Cellular
11	15111	Rythmic™ ULTIMA XL (Blue)	15011	Rythmic™ ULTIMA XL (Blue)
12	15112	Rythmic™ ULTIMA XL (Blue) Cellular	15012	Rythmic™ ULTIMA XL (Blue) Cellular

3.3 Accessories

Pos.	UDI-DI	Ordering Code (ERP)	Item Code	Item Name
1.	05206116003750	KM1.YY.547.1	81006	Rythmic S Carrying Shoulder Bag single use
2.	05206116005846	KM1.YY.566.1	81007	Rythmic XS Carrying Shoulder Bag single use
3.	05206116002623	KM1.YY.506.2	81008	Rythmic XS Carrying Waist Bag 250 mL
4.	05206116810136	KM1.YY.563.1	81013	Rythmic XS Carrying Shoulder Bag 1000 mL
5.	05206116005204	KM1.YY.491.2	81016	Rythmic XL Carrying Shoulder Strap
6.	05206116001541	KM1.YY.418.2	81017	Rythmic XL Carrying Shoulder Bag
7.	05206116003934	KM1.YY.548.1	81019	Rythmic XL Carrying Shoulder Bag single use
8.	05206116001473	KS5.01.524.3	81037	Rythmic Organizer Pole Clamp
9.	05206116000681	KS5.04.017.5	81039	Mini Rythmic Pole Clamp
10.	05206116810433	81043	81043	Rythmic Ultima Bolus Handset
11.	05206116001800	KP5.04.113.1	81047	Rythmic External Battery Pack
12.	05206116001503	KS5.04.021.2	81049	Rythmic Power Adaptor plug type G (UK)
13.	05206116001497	KS5.01.615.4	81052	Rythmic Power Adaptor plug type C (EU)
14.	05206116006577	KS5.04.046.1	81058	MicrelCom Cable (RS232 and USB)
15.	05206116007581	KS5.04.041.1	81059	Rythmic Power Adaptor plug type I (AU)
16.	05206116810600	81060	81060	Rythmic S Carrying Bag
17.	05206116007802	KS5.04.043.1	81065	Rythmic Power Adaptor plug type A (US)
18.	05206116810709	81070	81070	Rythmic Ultima/Serena Rechargeable Battery (spare)
19.	05206116810730	81073	81073	Rythmic Library Uploader

Pos.	UDI-DI	Ordering Code (ERP)	Item Code	Item Name
20.	05206116009882	81074	81074	Rythmic XS Carrying Bag
21.	05206116810754	81075	81075	Micrelcare

3.4 Harmonized European Standards

(Source: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02020D0437-20210415&from=EN)

Pos.	Document Description
1	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018
2	EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005) EN 60601-1:2006/AC:2010 EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)
3	EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014)
4	EN 60601-1-8:2007 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006) EN 60601-1-8:2007/AC:2010 EN 60601-1-8:2007/A11:2017
5	EN 60601-1-11:2010 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2010)
6	EN 60601-2-24:1998 Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers (IEC 60601-2-24:1998)
7	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
8	EN 62304:2006 Medical device software - Software life-cycle processes (IEC 62304:2006) EN 62304:2006/AC:2008
9	EN 62366:2008 Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)
10	EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)