

Doc Title:	Rythmic™ Evolution_Declaration Of Conformity MDD						
Doc #:	ML-PR-11026	Rev.:	3	Page:	1 of 1	Status:	Released
Type:						Unclassified Uncontrolled when printed or copied!	
Created by:	Sasa Karpeti		Ownership:	Regulatory Affairs			
Eff. Date:	Feb 4, 2020	Origin:	Internal	Owner:	Sasa Karpeti		
Item Name	Rythmic™ Evolution Model						
Item Code:	11000	Item Version:	8	Item ERP No.:	N/A	Item Level:	Model
Governance	Doc #:	Title				Revision	Released
Used Form	ML-TMP-00001	NA				NA	Jul 5, 2018
Governed WIN	ML-TMP-00001	NA				NA	Jul 5, 2018
Governed SOP	ML-TMP-00001	NA				NA	Jul 5, 2018
Filename:	ML-PR-11026_Rythmic™ Evolution_Declaration Of Conformity MDD_Rev.3.docx				Copy created:	2020-01-23	

1 Document Approval - Electronic Signatures

Christos Freris;Document Control Review;Friday, January 17, 2020 12:38:21 PM EET
 Achilleas Tsoukalis;Review;Tuesday, January 21, 2020 10:36:06 AM EET
 Sasa Karpeti;Final Approval;Tuesday, January 21, 2020 12:45:27 PM EET
 Christos Freris;Final Approval;Tuesday, January 21, 2020 12:56:14 PM EET

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 document

"ML-PR-11008_Rythmic™ Evolution_Registration_Item List"

- are in conformity with the essential requirements and principles for safety and performance of the **Medical Devices Directive 93/42/EEC ("MDD") amended by Council Directive 2007/47/EC**
- are classified Class IIb according to the Annex IX, rule 11, of the above directive
- are CE certified according to the conformity assessment and supervision of the

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

*Quality Assurance Manager
 Sasa Karpeti
 Karpeti*

This declaration is signed electronically and valid until 2022-03-03,
 the expiry date of the EC Full Quality Assurance System Certificate BG19/871877.

Doc Title:	Rythmic™ Evolution_Registration_Item List						
Doc #:	ML-PR-11008	Rev.:	2	Page:	1 of 2	Status:	Released
Type:	Item List						Unclassified Uncontrolled when printed or copied!
Created by:	Sasa Karpeti		Ownership:	Regulatory Affairs			
Eff. Date:	Feb 6, 2020	Origin:	Internal	Owner:	Sasa Karpeti		
Item Name	Rythmic™ Evolution Model						
Item Code:	11000	Item Version:	8	Item ERP No.:	N/A	Item Level:	Model
Governance	Doc #:	Title				Revision	Released
Used Form	ML-TMP-00001	NA				NA	Jul 5, 2018
Governed WIN	ML-TMP-00001	NA				NA	Jul 5, 2018
Governed SOP	ML-TMP-00001	NA				NA	Jul 5, 2018
Filename:	ML-PR-11008_Rythmic™ Evolution_Registration_Item List_Rev.2.docx					Copy created:	2020-03-30

1 Document Approval - Electronic Signatures

Christos Freris;Document Control Review;Thursday, December 19, 2019 10:39:00 AM EET
 Achilleas Tsoukalis;Review;Thursday, January 23, 2020 2:31:01 PM EET
 Sasa Karpeti;Final Approval;Thursday, January 23, 2020 2:38:32 PM EET
 Christos Freris;Final Approval;Thursday, January 23, 2020 2:39:39 PM EET

2 Sales Packs

Pos.	Item Ref. Nr.	Item Name
1	KP5.04.125.4	Rythmic Evolution (Blue)
2	KP5.04.130.3	Rythmic Evolution (Yellow)
3	KP5.04.141.4	Rythmic Evolution Organiser 500 (Blue)
4	KP5.04.147.4	Rythmic Evolution Organiser 500 (Yellow)
5	KP5.04.144.5	Rythmic Evolution Organiser 501 (Blue) Rechargeable
6	KP5.04.150.5	Rythmic Evolution Organiser 501 (Yellow) Rechargeable
7	KP5.04.136.4	Rythmic Evolution Rechargeable (Blue)
8	KP5.04.173.4	Rythmic Evolution Rechargeable (Yellow)
9	KP5.04.249.1	Rythmic Evolution Rechargeable (Yellow) UK
10	KP5.04.261.3	Mini Rythmic Evolution Lockable (Blue)
11	KP5.04.263.3	Mini Rythmic Evolution Lockable (Yellow)
12	KP5.04.265.3	Mini Rythmic Evolution Lockable Rechargeable (Blue)
13	KP5.04.267.3	Mini Rythmic Evolution Lockable Rechargeable (Yellow)
14	KP5.04.269.1	Mini Rythmic Evolution Lockable Rechargeable (Blue) UK
15	KP5.04.268.3	Mini Rythmic Evolution Lockable Rechargeable (Yellow) UK
16	KP5.04.151.5	Rythmic Evolution Organiser 501 UK (Blue) Rechargeable
17	KP5.04.152.5	Rythmic Evolution Organiser 501 UK (Yellow) Rechargeable
18	KP5.04.190.1	Rythmic Evolution Blue Rechargeable UK
19	KP5.04.186.1	Rythmic Evolution Blue Rechargeable No key
20	11141	Mini Rythmic Evolution Lockable (Blue) with Banana Bag

3 Accessories

Pos.	Item Ref. Nr.	Item Name
1	KS5.01.410.0	Bolus Switch
2	KS5.04.505.2	Evolution Bolus Handset
3	KS5.04.017.5	Pole Clamp mini Rythmic™
4	KS5.01.430.3	Rythmic™ holder with Pole Clamp
5	KS5.01.615.4	Micrel Power Adaptor nc
6	KS5.04.021.2	Micrel Power Adaptor UK plug nc
7	KS5.04.043.1	Micrel Power Adaptor USA type NEMA 1-15
8	KS5.04.110.3	Portable Printer with two cables nc

Doc Title:

Rythmic™ Evolution_Registration_Item List



Doc #:

ML-PR-11008

Rev.:

2

Page:

2 of 2

Status:

Released

9	KS5.04.186.1	MicrelPrint cord nc (for printer)
10	KS5.04.046.1	MicrelCom System (RS 232 and USB)
11	KP5.04.259.2	IP Connect Pack nc
12	KP5.04.271.1	IP Connect Pack nc with power adaptor
13	KP5.04.272.1	IP Connect Pack nc with UK power adaptor
14	KM1.YY.418.2	Carrying bag for Rythmic™ 500/501
15	KS5.01.524.3	Pole Clamp Rythmic™ 500/501
16	KP5.04.250.3	Rythmic Manager Pack
17	KM1.YY.415.2	Carrying bag for Rythmic™
18	KM1.YY.417.1	Carrying bag for Rythmic™ and IP Connect
19	KM1.YY.547.1	Disposable Carrying bag for Rythmic™
20	KM1.YY.566.1	Disposable Carrying bag for Mini Rythmic™
21	KM1.YY.548.1	Disposable Carrying bag for Rythmic™ Organiser 500/501
22	KM1.YY.506.2	"Banana" carrying bag 200ml for Mini Rythmic™
23	KM1.YY.400.1	Mini Rythmic™ Bag
24	KM1.YY.318.2	Carrying bag 500ml for Rythmic™ and IP Connect
25	KM1.YY.365.1	Mini Rythmic™ Bag 500 ml
26	KM1.YY.317.1	Isothermal carrying bag for Rythmic™ (PPH therapy)
27	KM1.YY.504.1	Carrying bag 500ml XL for Rythmic™ and IP Connect
28	KM1.YY.539.1	Carrying Bag 500ml for Two Rythmic™ Pumps