


Doc Title:	Rythmic™ Administration Set_Declaration Of Conformity MDD					
Doc #:	ML-PR-23029	Rev.:	6	Page:	1 of 4	Status: Released
Type:	Declaration Of Conformity					Unclassified Uncontrolled when printed or copied!
Created by:	Christos Freris		Ownership:	Regulatory Affairs		
Eff. Date:	May 31, 2021	Origin:	Internal	Owner:	Achilleas Tsoukalis	
Item Name	Rythmic™ Administration Set Model					
Item Code:	23000	Item Version:	7	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-23029_Rythmic™ Administration Set_Declaration Of Conformity MDD_Rev.6.docx				Copy created:	2022-07-13

1 Document Approval - Electronic Signatures

Christos Freris;Document Control Review;Jul 7, 2022 5:25 PM EEST
Eleni Lili;Review;Jul 8, 2022 9:08 PM EEST
Christos Freris;Final Edit;Jul 12, 2022 11:20 AM EEST
Achilleas Tsoukalis;Final Approval;Jul 12, 2022 11:50 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

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

Medical Devices Directive 93/42/EEC (“MDD”) amended by Council Directive 2007/47/EC

are classified Class IIa according to the Annex IX, rule 2 of the above directive

are CE certified according to the conformity assessment route

Annex XI, Chapter I & Section 4, Full QMS and Technical Documentation

and 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,
the expiry date of the EC Full Quality Assurance System Certificate BG19/871877.


3 ANNEX

3.1 Model

Pos.	Item Code	Item Name
1	23000	Rythmic™ Administration Set Model

3.2 Product Sales Packs and Variants

Pos.	Sales Pack		Contains Variant	
	Ref. Nr.	Sales Pack Name	Variant Ref Nr.	Variant Name
1	KS5.04.507.1	HyQvia ADMINISTRATION SET (6mm)	KM1.EE.148.0	Spike Set PN DEHP free
2	KS5.04.508.1	HyQvia ADMINISTRATION SET (9mm)	KM1.EE.148.0	Spike Set PN DEHP free
3	KE1.EE.185.9	Full Set 200mL	KE1.EE.185.9	Full Set 200mL
4	KE1.EE.220.1	Valve Extension Set with filter 0,2um	KE1.EE.220.1	Valve Extension Set with filter 0,2um
5	KE1.EE.195.9	Y Mini Full Set 100mL	KE1.EE.195.9	Y Mini Full Set 100mL
6	KE1.EE.196.9	Y Full Set 200mL	KE1.EE.196.9	Y Full Set 200mL
7	KM1.EE.099.1	Spike Set	KM1.EE.099.1	Spike Set
8	KM1.EE.155.9	Spike Set S	KM1.EE.155.9	Spike Set S
9	KM1.EE.187.9	Spike Set S Y	KM1.EE.187.9	Spike Set S Y
10	KM1.EE.148.0	Spike Set PN DEHP free	KM1.EE.148.0	Spike Set PN DEHP free
11	KM1.EE.139.0	Spike Set PN Gravity prime DEHP Free	KM1.EE.139.0	Spike Set PN Gravity prime DEHP Free
12	KE1.EE.134.9	Luer Set PN F DEHP Free	KE1.EE.134.9	Luer Set PN F DEHP Free
13	KE1.EE.192.9	Pediatric Spike PN Set DEHP Free 0,2um filter for 2 in 1 F	KE1.EE.192.9	Pediatric Spike PN Set DEHP Free 0,2um filter for 2 in 1 F
14	KE1.EE.179.2	Short Spike connecting line DEHP Free	KE1.EE.179.2	Short Spike connecting line DEHP Free
15	KE1.EE.225.1	Double Short Spike Connecting line with back check valve DEHP Free	KE1.EE.225.1	Double Short Spike Connecting line with back check valve DEHP Free
16	KE1.EE.226.1	Triple Short Spike Connecting line with back check valve DEHP Free	KE1.EE.226.1	Triple Short Spike Connecting line with back check valve DEHP Free
17	KE1.EE.171.4	Spike Set S AD for PN.PN+ Pumps	KE1.EE.171.4	Spike Set S AD for PN.PN+ Pumps
18	KE1.EE.178.2	Spike Set S Green	KE1.EE.178.2	Spike Set S Green
19	KE1.EE.339.1	Yellow Mini Full Set 100ml With NRFit® Connector	KE1.EE.339.1	Yellow Mini Full Set 100ml With NRFit® Connector
20	KE1.EE.340.1	Yellow Full Set 200ml With NRFit® Connector	KE1.EE.340.1	Yellow Full Set 200ml With NRFit® Connector
21	KE1.EE.337.1	Yellow Spike Set With NRFit® Connector	KE1.EE.337.1	Yellow Spike Set With NRFit® Connector
22	KE1.EE.338.1	Yellow Spike Set S With NRFit® Connector	KE1.EE.338.1	Yellow Spike Set S With NRFit® Connector
23	KM1.EE.148.1	Spike Set PN DEHP Free	KM1.EE.148.1	Spike Set PN DEHP Free
24	KE1.EE.196.0	Y Full Set 200mL	KE1.EE.196.0	Y Full Set 200mL
25	KE1.EE.192.0	Pediatric Spike PN Set DEHP Free 0.2um Filter for 2 in 1 F	KE1.EE.192.0	Pediatric Spike PN Set DEHP Free 0.2um Filter for 2 in 1 F
26	KM1.EE.139.1	Spike Set PN Gravity Prime DEHP	KM1.EE.139.1	Spike Set PN Gravity Prime

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		Free				DEHP Free	
27	KM1.EE.187.2	Spike Set S Y		KM1.EE.187.2		Spike Set S Y	
28	KM1.EE.148.9	Spike Set PN DEHP Free		KM1.EE.148.9		Spike Set PN DEHP Free	
29	KE1.EE.177.0	Mini Full Set 100mL		KE1.EE.177.0		Mini Full Set 100mL	
30	KE1.EE.185.1	Full Set 200mL		KE1.EE.185.1		Full Set 200mL	
31	KE1.EE.158.0	Short Set 100 mL		KE1.EE.158.0		Short Set 100 mL	
32	KE1.EE.195.1	Y Mini Full Set 100mL		KE1.EE.195.1		Y Mini Full Set 100mL	
33	KM1.EE.099.2	Spike Set		KM1.EE.099.2		Spike Set	
34	KM1.EE.155.1	Spike Set S		KM1.EE.155.1		Spike Set S	
35	KE1.EE.178.3	Spike Set S Green		KE1.EE.178.3		Spike Set S Green	
36	KE1.EE.197.0	Luer Set		KE1.EE.197.0		Luer Set	
37	KM1.EE.160.0	Yellow Spike Set		KM1.EE.160.0		Yellow Spike Set	
38	KM1.EE.162.0	Yellow Spike Set S		KM1.EE.162.0		Yellow Spike Set S	
39	KE1.EE.167.0	Yellow Mini Full Set 100mL		KE1.EE.167.0		Yellow Mini Full Set 100mL	
40	KE1.EE.190.0	Yellow Full Set 200mL		KE1.EE.190.0		Yellow Full Set 200mL	
41	KE1.EE.337.2	Yellow Spike Set With NRFit(TM) Connector		KE1.EE.337.2		Yellow Spike Set With NRFit(TM) Connector	
42	KE1.EE.338.2	Yellow Spike Set S with NRFit(TM) Connector		KE1.EE.338.2		Yellow Spike Set S with NRFit(TM) Connector	
43	KE1.EE.339.2	Yellow Mini Full Set 100mL with NRFit(TM) Connector		KE1.EE.339.2		Yellow Mini Full Set 100mL with NRFit(TM) Connector	
44	KE1.EE.340.2	Yellow Full Set 200mL with NRFit(TM) Connector		KE1.EE.340.2		Yellow Full Set 200mL with NRFit(TM) Connector	
45	KE1.EE.134.1	Luer Set PN F DEHP FREE		KE1.EE.134.1		Luer Set PN F DEHP FREE	
46	KE1.EE.171.5	Spike Set S AD for PN/PN+ Pumps		KE1.EE.171.5		Spike Set S AD for PN/PN+ Pumps	
47	KM1.EE.148.2	Spike Set PN DEHP FREE		KM1.EE.148.2		Spike Set PN DEHP FREE	
48	KE1.EE.345.1	Bag Set 200mL no filter		KE1.EE.345.1		Bag Set 200mL no filter	
49	KE1.EE.177.9	Mini Full Set 100mL		KE1.EE.177.9		Mini Full Set 100mL	
50	KE1.EE.158.9	Short Set 100mL		KE1.EE.158.9		Short Set 100mL	
51	KM1.EE.141.8	Valve Extension Set		KM1.EE.141.8		Valve Extension Set	
52	KE1.EE.197.9	Luer Set		KE1.EE.197.9		Luer Set	
53	KE1.EE.167.9	Yellow Mini Full Set 100mL		KE1.EE.167.9		Yellow Mini Full Set 100mL	
54	KE1.EE.190.9	Yellow Full Set 200mL		KE1.EE.190.9		Yellow Full Set 200mL	
55	KM1.EE.160.9	Yellow Spike Set		KM1.EE.160.9		Yellow Spike Set	
56	KM1.EE.162.9	Yellow Spike Set S		KM1.EE.162.9		Yellow Spike Set S	

3.3 Accessories

N/A

3.4 Applied Standards

Pos.	Doc ID	Doc Title
1.	ISO 13485:2016 (3rd Ed.)	Medical devices -- Quality management systems -- Requirements for regulatory purposes
2.	ANSI/AAMI/ISO/EN 14971:2012	Application of Risk Management to Medical Devices
3.	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
4.	EN ISO 15223-2:2010	Medical Devices – Symbols to be used with Medical Device labels, labeling and information to be supplied - Part 2: Symbol development, selection, validation
5.	ISO 11135: 2014	Sterilization of health care products – Ethylene oxide: Part 1 : Requirements for development, validation and routine control of a sterilization process for medical devices.
6.	ISO 11737-1: 2018	Sterilization of medical devices – Microbiological methods - Part 1: Determination of a population of microorganisms on products
7.	ISO 11737-2: 2019	Sterilization of medical devices – Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
8.	ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
9.	ISO 10993-4: 2017	Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002 including Amd.1:2006)
10.	ISO 10993-5: 2009	Part 5: Tests for in vitro cytotoxicity
11.	ISO 10993-7: 2008	Part 7: Ethylene oxide sterilization residuals
12.	ISO 10993-10: 2010	Part 10: Tests for irritation and delayed-type hypersensitivity
13.	ISO 10993-11:2017	Part 11: Tests for systemic toxicity (ISO 10993-11:2006)
14.	ISO 10993-12:2012	Part 12: Sample preparation and reference materials
15.	ISO 10993-17:2002	Part 17: Establishment of allowable limits for leachable substances
16.	ISO 10993-18:2020	Part 18: Chemical characterization of medical device materials within a risk management process.
17.	ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
18.	ISO 14698-1:2003	Cleanrooms and associated controlled environments - Part 1: General Principles and methods
19.	ISO 14698-2:2003	Cleanrooms and associated controlled environments - Part 2: Evaluation and interpretation of biocontamination data
20.	ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
21.	ISO 11607-2:2019	Packaging for terminally sterilized medical devices – Part 2 : Validation requirements for forming, sealing and assembly processes
22.	ISO 8536-8:2015	Infusion equipment for medical use — Part 8:Infusion sets for single use with pressure infusion apparatus
23.	ISO 80369-6:2016	Small bore connectors for liquids and gases in healthcare applications -- Part 6: Connectors for neuraxial applications
24.	USP 39	United States Pharmacopeia 39, National Formulary 33, 2015, <151> Pyrogen Test