EC DECLARATION OF CONFORMITY

1) Manufacturer: RITM OKB ZAO
Address: **99, Petrovskaya Str., Taganrog, 347900, Russia**
Tel.: **+7 863 4 62 31 79**

2) European authorized representative: SCENAR CENTER - BULGARIA ltd.
Address: **9, V. Aprilov blvd., Plovdiv, 4002, Bulgaria**
Tel.: **+3 59 32 641-001**

3) Product(s) *(name, type or model/batch number, etc.)***:**

Impulse therapy medical devices of TENS type (Transcutaneous Electric Nerve Stimulator)

CHANS-SCENAR	TS 9444-013-05010925-2002	*see appendix of Types*
SCENAR-NT	TS 9444-015-05010925-2004	*see appendix of Types*

4) GMDN Code: 35372

5) The product(s) described above is in conformity with:
DIRECTIVE
General Applicable Directive:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 Concerning medical device (MDD93/42/EEC+amendment 2007/47/EC) and following standards:

Standard
EN ISO 13485:2016
EN ISO 14971:2012
EN 1041:2008
EN ISO 15223-1:2016
EN 60601-1:2006/A1:2013
EN 60601-2-10:2015/A1:2016
EN 60601-1-2:2015
EN 60601-1-6:2010/A1:2015
EN 62304:2006/A1:2015
EN 62366:2008

6) Additional information :
Conformity assessment procedure for CE marking: Medical Device Directive, Annex II (excluding Section 4)
Notified Body and NB-no: 2265
3EC International a.s., Hraničná 18, Bratislava, 82105, Country: Slovakia.
EC Certificate number: 2017-MDD/QS-014/B
EC Certificate validity: March 07, 2022

Taganrog, Russia; 16-04-2019 ----------
Yuri Starovoytov, Director General of RITM OKB ZAO
(Place & date of issue) *(name; function and signature of manufacturer)*

Plovdiv, Bulgaria; 16-04-2019 ----------
Ognyan Landov, Director of SCENAR CENTER - BULGARIA ltd.
(Place & date of issue) *(name; function and signature of authorized representative)*

Appendix

Date: 16-04-2019

List of devices

Device name	Types	Trade (alternative) names	Risk class / rule[1]	First date of CE-marking
CHANS-SCENAR	CHANS-SCENAR	RITMSCENAR Home SCENAR Home	Class IIa / Rule 9	12-09-2006
	CHANS-01-SCENAR	RITMSCENAR Sport SCENAR Sport SCENAR Pain Genie RITMSCENAR Home Device RITMSCENAR Gorfinkel SCENAR Gorfinkel		
	CHANS-02-SCENAR	RITMSCENAR Basic SCENAR Basic		
	CHANS-SCENAR-M	RITMSCENAR Home D SCENAR Home D		
	CHANS-01-SCENAR-M	RITMSCENAR Sport D SCENAR Sport D		
	CHANS-02-SCENAR-M	RITMSCENAR Basic D SCENAR Basic D		
SCENAR-NT	SCENAR-1-NT (version 01)	RITMSCENAR Pro Prime SCENAR Pro Prime	Class IIa / Rule 9	12-09-2006
	SCENAR-1-NT (version 02.1)	RITMSCENAR Pro Plus RITMSCENAR Pro + SCENAR Pro Plus SCENAR Pro +		
	SCENAR-1-NT (version 02.2)	RITMSCENAR Pro Optima SCENAR Pro Optima		
	SCENAR-1-NT (version 02.3)	RITMSCENAR Pro SCENAR Pro		
	SCENAR-1-NT (version 03)	RITMSCENAR Pro Essential SCENAR Pro Essential		
	SCENAR-1-NT (version 01C)	RITMSCENAR Pro Prime C SCENAR Pro Prime C RITMSCENAR Super Pro v.2 bioSCENAR Professional v.2	Class IIa / Rule 9	20-12-2017
	SCENAR-1-NT (version 02.1C)	RITMSCENAR Pro Plus C RITMSCENAR Pro + C SCENAR Pro Plus C SCENAR Pro + C		
	SCENAR-1-NT (version 02.2C)	RITMSCENAR Pro Optima C SCENAR Pro Optima C SCENAR Physio		
	SCENAR-1-NT (version 02.3C)	RITMSCENAR Pro C SCENAR Pro C		
	SCENAR-1-NT (version 03C)	RITMSCENAR Pro Essential C SCENAR Pro Essential C		
	RITMSCENAR Expert		Class IIa / Rule 9	11-03-2019
	RITMSCENAR Expert C			

[1] See risk classification in Medical Device Directive, annex IX

Device name	Types	Trade (alternative) names	Risk class / rule[1]	First date of CE-marking
Add-on electrodes	Face electrode Comb electrode Point electrode Local electrode Special Snail electrode Bent point electrode Double facial Pawns electrode Double cosmetic electrode Double ophthalmic Goggles electrode Double facial Stamps electrode Single ophthalmic Monocle electrode Special double Pencils electrode Large Comb electrode Multi-purpose zonal electrode		Class IIa / Rule 9	30-06-2015