Rejûvaskin® A SKIN HEALTH COMPANY | ScarHeal

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Scar Heal	13191 Starkey Rd Unit 11 Largo, FL 33773 USA	

Name of Company	Address	SRN	Phone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	Code / Catalog Number
Scar Fx® Silicone Sheeting	10101 10122 11234 SG01A 11503 10305 13456 SG02A 11505 10408 15678 SG03A 11509 11012 10648 SG04A 10112 10000 SG05A SG09A
Intended Purpose	Basic UDI-DI
Scar Fx is indicated for use on epithelialized (closed) skin for the purpose of improving the appearance of surgical and traumatic scars.	642790SSS100AJ

RISK CLASS FOR DEVICES		
Device Classification		Common Specifications / Standards
Class:	1	Annex VIII of MDR (EU) 2017/745
Rule:	1	

Scar Heal declares that the above-mentioned products meet the provision of the following EU legislation:
Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Lori Brandon **TITLE:** Compliance Director

SIGNATURE: Lori Brandon **DATE:** 20 July 2021 **PLACE:** Tampa, Florida, USA

ATLANTIC MEDICAL PRODUCTS LLC LIMITED LIABILITY COMPANY SEAL 2016 FLORIDA

Document	Revision
SSS-DOC-002	07.01.2021