Rejûvaskin® | ScarHeal
A SKIN HEALTH COMPANY

ScarSil Silicone Scar Gel

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
RejuvaSil® Silicone Scar Gel a/k/a ScarSil® Silicone Scar Gel	80000 85000 85044 85815 80115 80002 85001 85102 85830 SG06A 80004 85004 85115 85801 SG08A 80010 85010 85804 85802 80015 85015 85810 85860
Intended Purpose	Basic UDI-DI
RejuvaSil®/ScarSil® is indicated for use on epithelialized (closed) skin for the purpose of improving the appearance of surgical and traumatic scars.	642790SSG8008Z

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:** 29 July 2021 **PLACE:** Tampa, Florida, USA

ATLANTIC MEDICAL PRODUCTS LLC LIMITED LIABILITY SEAL 2016 FLORIDA COMPANY

Document	Revision
SSG-DOC-002	07.20.2021