

DECLARATION OF CONFORMITY

Declaration No.:	10/2021
Manufacturer:	HELP S.A. Office's address: 10 Valaoritou, Metamorfosi, 14452 Greece Facility address: Pedini Ioanninon, Ioannina, 45500 Greece
Products:	<u>Product:</u> Resin Salve <u>Product types:</u> 1. Abilar 5%, 4. Sutriheal Forte 5% 5% resin ointment is used for the local treatment of infected and uninfected wounds at home or professionally. Wounds can be acute or chronic: e.g., abrasions, broken skin, cracks, burn wounds or open blisters. 2. Abilar 10%, 3. Sutriheal Forte 10% 10% resin salve is used for the local treatment of infected and uninfected wounds at home or professionally. Wounds can be acute or chronic: e.g., abrasions, broken skin, cracks, burn wounds, pressure or diabetic wounds, surgical wound complications or open blisters.
Classification:	5% resin ointment (1. Abilar 5%, 4. Sutriheal Forte 5%): IIa 10% resin salve (2. Abilar 10%, 3. Sutriheal Forte 10%): IIb
Classification rules:	Rule 4, Annex IX, Directive 93/42/EEC
Notified Body (NB):	NATIONAL EVALUATION CENTER OF QUALITY AND TECHNOLOGY IN HEALTH S.A. - EKAPTY Identification number: 0653 Address: Stadiou 10 & Omirou 4 Athens, Greece (current) Smyrnis 15, 165 62 Glyfada, Greece (previous address until 30/6/2021)
Conformity assessment procedure:	Directive 93/42/EEC, Annex II (Full quality assurance)
EC certificate number:	302011018TN
EC certificate validity:	20/05/2024

Help S.A. hereby declares that the Declaration of Conformity is issued under the sole responsibility of the manufacturer, in accordance with the Directive 93/42/EEC and the specific requirements of the Medical Device Regulation 2017/745 for devices with certificate issued in accordance with the Directive 93/42/EEC.

For HELP S.A.

Date: 6/10/2021, Place: Metamorfosi, Greece

Signature:

Evangelos Zekkas

President & CEO of HELP S.A.

