EC DECLARATION OF CONFORMITY

Declaration No.: **0X-201X**

Manufacturer: SGM d.o.o.
G. Novaka 22a
21000 Split, CROATIA

Product Name: IOM ELECTRODES
Model/Type: CORK SCREW, SUBDERMAL NEEDLE, HOOK WIRE
Classification: IIa (Annex IX, Rule 6)

SGM d.o.o. HEREBY STATES THAT ABOVE MENTIONED PRODUCT COMPLY WITH THE ESSENTIAL REQUIREMENTS OF MEDICAL DEVICE DIRECTIVE 93/42/EEC.

The product was a subject of conformity assessment procedure described in Annex II (Full quality assurance system), excluding section 4.

Standards applied:
EN ISO 13485: 2012
EN ISO 14971: 2012
EN ISO 15223-1:2016
EN 60601-1-6_2011_A1_2015
EN 60601-2-40: 1998
EN ISO 11135-1:2007
EN ISO 11607-2:2006
EN 62366:2008
EN 1041:2008

Regulative applied: The Recast RoHS Directive RoHS 2.0; category 8; monitoring category 9

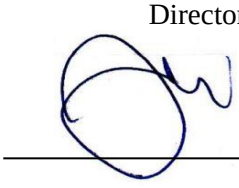
DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE)

Notified body: SIQ, Slovenian Institute of Quality and Metrology
Tržaška cesta 2
1000 Ljubljana, SLOVENIA
Notified Body No. 1304

EC Certificate: No: 1304-MDD--153
Issue: 1/2019-12-19
Valid until: 2024-05-28

SPLIT, 20.12.2019

INA JAKELIĆ
Director:



Ina Jakelić, oec.