We, **the Manufacturer**

Manufacturer name: Joint Stock Company «MedSil», JSC «MedSil».
Legal address: Novomytishchinsky prospect, 41 A, town of Mytishchi, Moscow region, Russia, zip 141018.
Mfg. Site: 24 Institutskaya St., Remmash village, Moscow region, 141336, Russia
Postal address: town of Myitishchi, Moscow region, Russia, zip 141002, P.O.Box 26
Tel/fax: +7-495-583-36-62
e-mail: medsil.zao@gmail.com
web site: www.medsil.ru

Represented in European Economic Community by

Name of European Authorized representative name and address: **OBELIS S.A** ,
Registered Address: Bd. Général Wahis, 53, 1030 Brussels, Belgium
Registered Office Address : Avenue de Tervuren, 34, bte 44 ,1040 Brussels, Belgium
Tel: +32.2.732.59.54 , Fax: +32.2.732.60.03
E-mail: mail@obelis.net
web site: www.obelis.net

herewith declare that our product fulfills requirements of Council Directive 93/42/EEC as amended by 2007/47/EC Annex II, excl. cl. 4

Product name: **A SET OF SILICONE DEVICES FOR GASTRIC RESTRICTION "MedSil Intragastric Balloon"**
Conformity assessment procedure: The device is the subject of procedure described in Annex II (except clause 4) of the Directive 93/42/EEC for medical devices (full system of quality assurance).
Risk Class/ Rule: Class IIb/ Rule 5
GMDN: 17202

The above product (s) meets the requirements of the following harmonized standards:

- EN ISO 13485:2016
- EN ISO 14971:2012
- EN ISO 10993-1:2009
- EN ISO 10993-5:2009
- EN ISO 10993-6:2009
- EN ISO 10993-11:2009
- EN ISO 10993-12:2012
- EN ISO 15223-1:2016
- EN ISO 1041:2008

Notified Body

The Name of Notified Body: **3EC International a.s.**
Notified Body Number: 2265
NB Adress: Hraničná 18, 821 05 Bratislava, Slovak Republic
Phone: +421 (0)2 5831 8343, Fax: +421 (0)2 5831 8345
E-mail: info@3ec.sk
web site: www.3ec.sk

Mytishchi, Russia Date: 18.02.2019

General Manager
JSC «MedSil»
Dmitry Zinenko