

# MEDICAL DEVICE FILE

PRODUCT NAME  
**GOLABACT® MED**

PROJECT  
**1016**

REF  
**1016**

TF NUMBER  
**TF006**

ISSUE NUMBER  
**00**

DATE  
**18.04.2019**

## 10 Declaration of Conformity

**Metis Healthcare s.r.l.**

Via della Moscova 13, Milan, 20132, Italy

Declares under its responsibility that following medical devices

Device Destination of use	REF(s)	GMDN	Risk Class	Rule
<b>Golabact® MED</b> Oral soluble tablets to protect oral mucosal against adhesion of pathogenic organisms and maintenance of the physiological conditions of oral mucosa and teeth.	1016	47943	I	5

comply with the essential safety requirements of the following standards:

**European Directive 93/42/CE as modified by EU Directive 2007/47/CE**  
D.Lgs n°46 del 27/02/1997 and further modification and amendments

Notified Body: \

Place: Milan (Italy)

Date: 18.04.2019

Revision date: Rev. 0 18.04.2019

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