



QUALITY MANAGEMENT SYSTEM  
UNI EN ISO 9001:2015  
UNI CEI EN ISO 13485:2021  
CERTIFIED BY CERTIQUALITY

COMPANY INSPECTED BY CERTIQUALITY  
FOR THE COMPLIANCE TO  
**GMP**  
CODE OF FEDERAL REGULATION,  
TITLE 21, VOLUME 2, PART 111



## EU DECLARATION OF CONFORMITY

### EU REGULATION (EU) 2017/745

The undersigned Company

Labomar S.p.A. a socio unico, Via N. Sauro 35 I, Istrana (TV), Italy

Reg. number (MDR Art.31): **IT-MF-000007965**

Legal Manufacturer of the Medical Device

<b>Device name:</b>	MD Cough syrup sugar free
<b>Tradename</b>	Bisolnatural 3 in 1
<b>REF:</b>	FTPR65
<b>BASIC UDI-DI:</b>	805630062FTPR659U
<b>Packaging size:</b>	100 ml bottle
<b>Destination of use:</b>	Bisolnatural 3 in 1, is a medical device composed of substances, not sterile, intended for short term invasive contact with respect to body orifices (oral cavity), designed for the treatment of wet and dry cough, throat irritation. Cough syrup MD sugar free is for children (2+), adolescents and adults. Its specific formula creates a protective film that calms the cough, protects from irritation improving the functionality of upper respiratory tract. In case of dry cough associated with sore throat, works by calming irritation, protecting the mucous membrane and aiding in the removal of mucus. In the case of a productive cough, it promotes the hydration of the mucus and facilitates its physiological expectoration.
<b>Risk Class:</b>	Ila
<b>Rule (MDR Annex VIII):</b>	21
<b>GMDN:</b>	47276
<b>Code(s) (EU) 2017/2185:</b>	MDN1213

Declares under its sole responsibility that the above mentioned Device complies to EU Regulation (EU) 2017/745 as amended by EU Regulation (EU) 2020/561.

<b>Conformity assessment procedure:</b>	Annex IX, capo I,III
<b>Notified body:</b>	"Eurofins Product Testing Italy s.r.l." (Via Cuorgnè, 21 10156 Torino, Italy) no. 0477
<b>CE certificate no.:</b>	EPT 0477.MDR.24/5564
<b>CE certificate expiry date:</b>	14/06/2028

Istrana (TV), Italy  
Date: 17/06/2025

Davide Nenzioni  
Group Regulatory Director & R&D Director  
Labomar S.p.A. a socio unico

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