DECLARATION OF CONFORMITY TO REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

MANUFACTURER: GRUPPO FARMAIMPRESA S.r.l.

SRN: IT-MF-000012625

BASIC UDI-DI: 805574884 FTCE16-26 7U

The underigned GRUPPO FARMAIMPRESA SRL with registered office in Via Cipro,1 – Brescia – Italy and operative site in Via Consortile ASI – Complesso VEGA 1 - Teverola,

Manufacturer of the IIb class medical device identified as:

Name	Description
tetesept Baby Bäuchlein Entspannungstropfen	Bottle of 20 ml

Type: Medical devices for oral use based on simethicone emulsion in olive oil solution.
With the following intended use: medical device indicated in the treatment and prevention in case of: Dyspeptic disorders, Gastroenteric meteorism, Aerophagy and Gaseous colic in infants, children and adults.

DECLARES

Under its own responsibility, that:

- ✓ The above device complies with all the applicable provisions of the aforementioned Regulation 2017/745;
- ✓ he above device belongs to class IIb of medical devices according to Rule 21, indent 4 (Devices consisting of substances or combinations of substances intended to be introduced into the human body which achieve their intended use in the lower gastrointestinal tract and they, or their metabolic products, are not systemically absorbed by the human body) as set out in Annex VIII (classification rules) Chapter III of Regulation 2017/745;
- ✓ For it a proper CE mark of conformity n. 010-00-02-MDR has been issued by the Notified Body Italcert n. 0426, date of issue 07/06/2023, expiry date 09/01/2028, current emission 23/03/2023 following conformity assessment procedure according to Annex IX Chapter I of Regulation 2017/745.

It undertakes to store and keep available to the Notified Body the technical documentation relating to the medical device for which this declaration of conformity has been drawn up, for a period of at least 10 years from the last date of placing on the market of the last batch or serial number of devices indicated.

It is hereby declared that the device in question complies with the aforementioned Regulation (EU) 2017/745 of 5 April 2017 on medical devices.

Brescia, 07/09/2023

Signature,_____ Name and function: CEO and Person responsible for regulatory compliance

GRUPPO FARMAIMPRESA srl
Via Cipro, 1 - 25124 BRESCIA
N° Verde 800 912 951
P. IVA e C.F. 05534151211
info@farmaimpresa.it

GruppoFarmaImpresa