New.Fa.Dem.

V.le Ferrovie dello Stato, 1 - zona ASI
80014 Giugliano in Campania (NA) – Italy

CE CONFORMITY DECLARATION
93/42/CEE, as modified by the amendment 2007/47/CE

Referenced to the Medical Device
"EASYLAX NEW.FA.DEM. MICROCLISMA GR. 3 BAMBINI" code 70014 and with the following commercial variant:

- *"Pomoli 3g" code 70479*
- *"Eurospital 3g" code 70469*
- *"Glicerol Inteli 3g" code 70502*
- *"Microcell 3g" code 70608*
- *"Assista 3g" code 70609*
- *"Sintofarm 3g" code 70611*
- *"4Lax 3g" code 70613*
- *"Milax-m 3g" code 70615*
- *"Osmoforce Lax G 3g" code 70626*
- *"FertoLax 3g" code 70631*
- *"Laxik 3g" code 70639*

Giugliano in Campania (NA), 12.02.2024

The company New.Fa.Dem. Srl, represented by Maria Goncharova (CEO) with legal office in Giugliano in Campania (NA), Viale Ferrovie dello Stato, 1 – Zona ASI 80014, declare under his own responsibility to be the manufacturer of the medical devices *"EASYLAX NEW.FA.DEM. MICROCLISMA GR. 3 BAMBINI","Pomoli 3g", "Eurospital 3g", "Glicerol Inteli 3g", "Microcell 3g","Assista 3g","Sintofarm 3g","4Lax 3g", "Milax-m 3g", "Osmoforce Lax G 3g", "FertoLax 3g" and "Laxik 3g"*

It is also declared that:

- We herewith declare that the above mentioned product meet the provisions of the Council Directive 93/42/EEC and 2007/47/EEC for Medical Device;
- The present medical device belongs to the class I according to the rules 5 of the Annex IX – Amendment 93/42/EEC (introduced in Italy with the Legislative Bill dated 24 February 1997, nr. 46 and succeeding modifications);
- The present medical device did not include any substance, which, if used separately, could be considered a medicine according to the art. 1 of the Bill 65/65/EEC;
- The present medical device is commercialized as NOT STERILE;
- The related medical device IS NOT A MEASURE INSTRUMENT;
- The related medical device IS NOT DESTINATED FOR CLINICAL INVESTIGATION;
- The manufacturer observed all dispositions applicable of the annex I and VII of Directive 93/42/EEC.

Harmonized Rules in compliance with the declaration:
UNI CEI EN ISO 14971:2012 *Application of risk management to medical devices.*
UNI CEI EN 1041:2013 *Information supplied by the manufacturer of medica devices. (Non-harmonized standard – the harmonized standard is previous version of 2008).*
UNI CEI EN ISO 15223-1:2017 *Medical devices - Symbols to be used with medical device. labels, labelling and information to be supplied - Part 1: General requirements.*
UNI CEI EN ISO 13485:2016 - *Medical devices -Quality management systems.*
UNI EN ISO 10993-1:2010 - *Biological evaluation of medical devices - Part 1:Evaluation and testing within a risk management process.*
This Conformity Declaration is valid only for above mentioned devices and used in a proper way as specified in the technical and security data sheet.

New.Fa.Dem. s.r.l.
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