



CE Declaration of conformity  
in accordance with the annex IV of the Regulation 2017/745  
relating to medical devices.

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Guarantees and declares under its sole responsibility that GRIPOBALLS and Mini-GRIPOBALLS, in accordance with Annex VIII of the European Regulation 2017/745, comply with the requirements for Class 1 medical devices.

This declaration is based on the following elements:

**Technical documentation**

See Annex II and III  
See monitoring

**Risk management**

The Medical Devices (GRIPOBALLS and Mini-GRIPOBALLS) consists of a plastic sphere (PVC). The additive used to soften PVC is used for soft toys and safe medical applications (phthalate free and compliant with DIN EN71-3 "Safety of toys").

And according to European Directive 2002/72 EC its use is permitted in food contact applications.

Each M.D. and M.D. accessories are accompanied by a usage document.

The M.D. meets functional requirements and is not hazardous.

**UDI-DI**

GRIPOBALLS (01)05430000493000

Mini-GRIPOBALLS (01)05430000493192

Valid until May 25, 2025

Brussels, March 29, 2021

A handwritten signature in blue ink, consisting of several overlapping loops and strokes, positioned below the date.