CE Declaration of conformity

according to Annex VII of Directive 93/42 / EEC
relating to Class 1 medical devices.

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Guarantees and declares, under its sole responsibility, that the Class 1 devices GRIPOBALLS and GRIPOgram pursuant to Annex VII of the European Directive 93/42 / EEC complies with the requirements of Directive 93/42 / EEC as amended by the Directive 2007/47 / EC.

This declaration is based on the following elements:

Technical documentation

(on demand)

Risk management

The M.D. (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.

The accessories of the M.D. (GRIPOgram) are made of stainless steel balls AISI 316L and are intended only for the ballast of the M.D. (GRIPOBALLS).

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

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

Brussels, 18 May 2016