

DECLARATION OF CONFORMITY

The undersigned Francesco Turchetta, acting as the Legal Representative of the company MARSHAL INTERGROUP S.R.L., fully addressed in Roma, Via Laurentina 855, declares, under its own responsibility, that following medical devices “soft contact lenses”:

Daily Spherical (Innofilcon A) 45 %	GENERIC 5 pcs (A55) With labels: LensGemak
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belonging to the risk class IIa, according to the rule 5 of the Annex IX of the Directive 93/42/EEC and further amendments (enforced in Italy with Legislative Decree 46/97 and further amendments), as amended by the Directive 2007/47/EC (enforced in Italy with Legislative Decree 37/10):

- Comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as per Technical File No. FT 05 kept on the premises of the company;
- Are manufactured according to the Quality System that satisfy the requirements of the Annex V of the above mentioned Directive, as per EC Certificate No. G2 003151 0002 Rev. 00 issued on 05/12/2019 by TUV SUD Product Service, Notified Body No. 0123, Ridlerstrasse 65, 80339 Munchen, Germany, valid until 26/05/2024.
- comply with EU Regulation 2017/745 regarding the requirements applicable to legacy devices in Art. 120(3)

In the Device Technical File there is the list of relevant harmonized standards.

Marshal Intergroup srl
Francesco Turchetta
General Manager

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Rome, 20/03/2026

This declaration of conformity has yearly validity.