



versalis

Direzione e Uffici Amministrativi

Piazza Boldrini, 1 - 20097 San Donato Milanese (MI)

Tel. centralino: +39 02 5201

www.versalis.eni.com - info@versalis.eni.com

PHARMACOPOEIA COMPLIANCE STATEMENT

PHARMALENE MT 10 PH

Our mentioned product, as supplied in original sealed packaging, complies with the applicable requirements of the pharmacopoeia monographs listed below:

- **European Pharmacopoeia:** EP 3.1.3 “Polyolefins” (10th edition – 2020); EP 3.1.4 “Polyethylene without additives for containers for preparations for parenteral use and for ophthalmic preparations” (10th edition – 2020).
- **United States Pharmacopoeia:** USP 41 <661.1> “Plastic materials of construction”.

The above mentioned product does not contain any recycled material.

The end-user has to ascertain that the final item is suitable to come into contact with the intended pharmaceutical products, in the expected use conditions, performing the specific tests prescribed by the pharmacopoeia monographs and by the relevant approval procedures.

Product Compliance Mgr.
Salvatore Minardi

This statement is valid three years and replaces those issued earlier.
Revision 16/03/2020.

versalis spa

Sede Legale: San Donato Milanese (MI) - Piazza Boldrini, 1 - Italia

Capitale sociale interamente versato: Euro 1.364.790.000,00

Codice Fiscale e registro Imprese di Milano 03823300821

Part. IVA IT 01768800748

R.E.A. Milano n. 1351279

Società soggetta all'attività di direzione

e coordinamento di Eni S.p.A.

Società con socio unico