versalis

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PHARMACOPOEIA COMPLIANCE STATEMENT

PHARMALENE MS 20 PH, MS 40 PH, MR 50 PH

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

- **European Pharmacopoeia**: EP 3.1.3 “Polyolefins” (10th edition – 2020); EP 3.1.5 “Polyethylene with additives for containers for preparations for parenteral use and for ophthalmic preparations” (10th edition – 2020).

The above mentioned products do not contain any recycled materials.

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.

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San Donato Milanese, 08/11/2019

Pharmalene MS 20 PH, MS 40 PH, MR 50 PH
ISO 10993 standards, USP Class VI; USP 42 <661.1>

We confirm that our LLDPE grades in subject successfully fulfilled the following biocompatibility tests:

- Cytotoxicity - ISO 10993-5, MEM-Elution test (USP <87>)
- Intracutaneous reactivity - ISO 10993-10, USP <88>
- Acute systemic toxicity - ISO 10993-11, USP <88>
- Muscle implantation and histopathology - ISO 10993-6, USP <88>

- USP 42 <661.1> “Plastic materials of construction”.

The studies, completed in 2019, were performed by a third party testing facility.

Under the conditions of the studies it can be stated that the mentioned Pharmalene grades meet the requirements of the mentioned ISO 10993 parts and of USP Class VI at 50°C.

Pls. note that the above results do not represent a warranty regarding the performance of final items manufactured with our mentioned materials; biocompatibility testing has to be performed by the end-user on the final item, according to the expected use conditions, to verify the compliance with the applicable regulatory limits.

Yours sincerely.

Product Compliance Manager
Salvatore Minardi

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