

EU DECLARATION NO:

PPWR-DoC-HDPE-B-01

Date

06.08.2026

Product Identification

Unique identification of the packaging

Rigid Plastic Bottle Packaging (Material Code: HDPE 02 / PP 05)

Manufacturer name and address

(350ml and 50ml primary plastic containment bottles/sprayers with closures)
ACTO GmbH

Sole responsibility statement

Schulstr. 8, 31613 Wietzen, Germany
This declaration of conformity is issued under the sole responsibility of the manufacturer. (ACTO GmbH).

Object of the Declaration

Description of packaging

Primary rigid plastic packaging manufactured for the direct containment of Hydroclean Solution (350ml), Tiritas Spray (50ml), Dermaplast Spray (50ml), and Cosmos Spray (50ml).

Primary rigid sales packaging engineered for medical/hygiene liquid and spray products under ACTO GmbH, comprising HDPE virgin resin body (Uz-Kor BL6200), PP closure (LyondellBasell EP548Q), and white masterbatch (Ideal 12140), classified as contact-sensitive medical packaging pursuant to PPWR Art. 3(49) and Regulation (EU) 2017/745.

Relevant Union Legislation

Reference to Regulation (EU) 2025/40 and applicable articles

Regulation (EU) 2025/40, as applicable to the packaging identified above. The conformity assessment addresses Article 5 (substances in packaging), Article 6 (recyclable packaging), Article 7(4)(b) (mandatory recycled content exemption for contact-sensitive medical device packaging covered by Regulation (EU) 2017/745), and Article 10 (packaging minimisation), together with the manufacturer obligations, conformity assessment and EU declaration requirements applicable under the Regulation. Applicability, transition dates and any implementing or delegated acts shall be verified and documented before the packaging is placed on the Union market.

Harmonized Standards

Harmonised standards applied

Technical specifications and assessment methods applied, subject to verification of their current status and suitability:

- EN 13428:2004 — prevention by source reduction.
- EN 13430:2004 — packaging recoverable by material recycling.
- EN 13431:2004 — packaging recoverable through energy recovery.
- Regulation (EC) 1935/2004: Materials intended to come into contact with sensitive products.

The above documents are not represented here as harmonised standards conferring a presumption of conformity unless their citation and legal effect have been confirmed for Regulation (EU) 2025/40.

References to common specifications used

- Uz-Kor Gas Chemical MSDS/TDS: HDPE BL6200 Virgin Resin Technical Sheet
- LyondellBasell TDS: PP Moplen EP548Q Impact Copolymer Technical Sheet
- Senta Plastik REACH Declaration: SVHC Candidate List 0.1\% {w/w} Compliance
- Ideal Masterbatch 12140 Statement: Chemical Safety and Heavy Metal Compliance

Additional Information

Place and Date of Issue

Wietzen, Germany — 06.08.2026

Name, Function (Signature)

Dr. Hasan Cicek

Quality Assurance & Regulatory Affairs Manager

Authorised to sign this EU Declaration of Conformity for and on behalf of ACTO GmbH.

Signature: _____

ACTO GmbH
Schulstrasse 8 | 31613
Wietzen-Holte | GERMANY
☎: +49 (0) 5022 9801-0 📠: +49 (0) 5022 9801-37
🌐: www.actogmbh.com ✉: info@actogmbh.com

