ACTO GmbH
Schulstr. 8
31613 Wietzen-Holte
Germany
www.actogmbh.com
info@actogmbh.com
Tel.: +49 (0) 531-239 508 0
Fax: +49 (0) 531-239 508 11

EU DECLARATION NO:	PPWR-DoC-FCB-01
Date	06.08.2026
Product Identification	
Unique identification of the packaging	ACTO folding-carton secondary/sales packaging, material code PAP 21, limited to the following product and nominal-fill variants: HydroClean Solution 350 ml; Tiritas Wound Spray 50 ml; DermaPlast Wound Spray 50 ml; and Cosmos Wound Spray 50 ml.
Manufacturer name and address	ACTO GmbH Schulstr. 8, 31613 Wietzen, Germany
Sole responsibility statement	This declaration of conformity is issued under the sole responsibility of the manufacturer. (ACTO GmbH).
Object of the Declaration	
Description of packaging	Custom-printed folding boxboard used as secondary/sales packaging for the containment, physical protection and presentation of the product variants listed under Product Identification. Small folding boxboard packaging custom manufactured for ACTO GmbH product lines, composed of Metsä Board virgin fibre paperboard (94.94%), Sun Chemical oil-based ink (1.76%), Actega dispersion/spot varnish (3.08%), and EUKALIN adhesive (0.22%).
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) 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 at the date 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:

ACTO GmbH
Schulstr. 8
31613 Wietzen-Holte
Germany
www.actogmbh.com
info@actogmbh.com
Tel.: +49 (0) 531-239 508 0
Fax: +49 (0) 531-239 508 11

Document No: PPWR-DoC-FCB-01 First Publication: 06.08.2026 Revision Date: - Revision No: 00

References to common specifications used	• EN 13428:2004 — prevention by source reduction. • EN 13430:2004 — packaging recoverable by material recycling. • EN 13431:2004 — packaging recoverable through energy recovery. • EuPIA GMP — good manufacturing practice for printing inks. 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. **Independent test evidence** • SGS test report TR2812751 — cumulative heavy metals (<100 ppm) and fluorine/PFAS (F < 50 ppm) screening. **Supplier declarations** • Sinangin Printing SVHC Declaration, 04.02.2026 — supplier statement regarding the REACH Candidate List threshold. • Sinangin PPWR Declaration, 18.06.2026 — supplier statement regarding recyclability; not an independent certification of 100% recyclability. • ACTEGA (Lehrte) Statement, 05.02.2026 — supplier statement regarding PFAS and heavy metals in the coating. • EUKALIN Statement, 05.06.2026 — supplier statement covering adhesive series 6325 VL 800, 6462 VL and 7185 VL 100. • Sun Chemical Statement, 2026 — supplier statement regarding printing-ink chemical safety. • Metsä Board Material Circularity Statement — Cepi Methodology 100% Virgin Fibre Recycling Score (92-100/100). **Manufacturer assessment** • Declared composition: virgin-fibre paperboard 94.94%, oil-based ink 1.76%, dispersion/spot varnish 3.08% and adhesive 0.22%; total 100.00%. • Recycled content: 0%, based on the declared virgin-fibre board composition. • Recyclability conclusion: the packaging is assessed as designed for material recycling, subject to the cited method, the tested configuration and confirmation of collection, sorting and recycling

ACTO GmbH
Schulstr. 8
31613 Wietzen-Holte
Germany

www.actogmbh.com
info@actogmbh.com
Tel.: +49 (0) 531-239 508 0
Fax: +49 (0) 531-239 508 11

	conditions; no unconditional 100% recyclability claim is made. • Article 5 conclusion: compliance is supported by the independent report and supplier declarations identified above, each limited to its stated scope and validity. • Article 10 conclusion: minimisation shall be supported by a documented design review showing that weight and volume do not exceed what is necessary for packaging functionality. Before signature, the technical file shall record for every cited item: issuer, exact title, document number, issue date, revision, covered material/product variant, assessment outcome and controlled storage location.
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