



## Poli International Co., Ltd

Precision Engineering for Body Arts  
Ratchaburi, Thailand  
patrick@poli-international.com | poliinternational.com

# REACH SVHC Declaration

Article 33 Compliance Statement — BioFlex Body Jewelry

<b>Document Reference:</b>	PI-REACH-2026-001
<b>Issue Date:</b>	April 6, 2026
<b>Valid Until:</b>	Next Candidate List update (review due July 2026)
<b>Applicable Regulation:</b>	Regulation (EC) No 1907/2006 (REACH), Article 33
<b>Reference List:</b>	ECHA Candidate List of SVHCs — 253 substances as of February 4, 2026

### Product Scope

This declaration covers all BioFlex® branded body jewelry products manufactured and supplied by Poli International Co., Ltd, including but not limited to: labret studs, barbells, nose screws, retainers, and all associated BioFlex® components.

### Material Classification

BioFlex® is a proprietary medical-grade biocompatible random copolymer. It is NOT PVC, NOT acrylic (PMMA), NOT nylon, and NOT TPU. The material has been certified to:

- **United States Pharmacopeia (USP) Class VI — Biocompatibility**
- **ISO 10993 — Biological evaluation of medical devices**
- **European Pharmacopoeia, 5th Edition, Monograph 3.2.2**
- **U.S. FDA Drug Master File assigned**

## DECLARATION

Poli International Co., Ltd hereby declares that, based on our current knowledge and the information available from our supply chain, all BioFlex® branded products listed in the scope above:

**DO NOT CONTAIN any Substance of Very High Concern (SVHC) included on the ECHA Candidate List (253 substances as of February 4, 2026) in a concentration above 0.1% weight by weight (w/w).**

This declaration is made in accordance with Article 33(1) of Regulation (EC) No 1907/2006 (REACH).

Note regarding trace substances: The production process may result in trace amounts of certain phthalates (DEHP, DBP, DIBP) from the catalyst system, typically at concentrations below 1 ppm (0.0001% w/w). These levels are well below the 0.1% (1,000 ppm) reporting threshold under REACH Article 33.

Trade Secret Notice: Due to trade secret and trademark protection under EU Directive 2016/943, the exact material source and formulation details of BioFlex® are proprietary and confidential. This declaration provides all information required under REACH Article 33. A confidential compliance dossier is available for regulatory audit upon request under non-disclosure agreement.

## Commitment

Poli International Co., Ltd commits to:

- Reviewing this declaration against each update of the ECHA Candidate List
- Issuing an updated declaration within 6 months of any relevant Candidate List change
- Providing consumers with this information upon request within 45 days, as required by Article 33(2)

Signature:



**Patrick Poli**

Director

Poli International Co., Ltd

Date: April 6, 2026

