

Apeldoorn,

30 July 2025

Etigam conformance declarations summary

To whom it may concern,

With reference to the current regulations as mentioned in the list underneath we declare to the best of our knowledge that the sterilization process indicators Etigam bv supplies; complies with or do not contain components as mentioned in the individual listings.

New added substances on the several listings are assessed on regular basis.

We will inform you and handle according the individual regulation if our components used are mentioned in updated listings.

- Substances according to REACH candidate list (SVHC). [Candidate List of SVHC for Authorisation - ECHA](#)
- Substances according to REACH Annex XIV [Authorisation List - ECHA](#)
- Substances according to REACH Annex XVII [Substances restricted under REACH - ECHA](#)
- Substances according to RoHS directive EU RoHS 3 (EU) 2015/863.
- No substances which meet the criteria as defined In Annex XIII that are PBT or vPvB [PBT assessment - ECHA](#)
- CMR substances, category 1A or 1B, in a concentration above 0,1% weight by weight (w/w) according to part 3 of annex VI to regulation (EC) No. 1272/2008 (CLP).
- PFAS substances as defined in restriction proposal (Annex XV) and as defined in TSCA section 8(a)(7)
- Persistent organic pollutants (POP`s): According to regulation (EU) 2019/1021.
- Substances listed under California Proposition 65 components above the Not Significant Risk Levels (NSRLs) for cancer-causing chemicals and maximum allowable dose levels (MADLs) for chemicals causing reproductive toxicity.
- No use of phthalates.
- No use of latex.
- No use of tissues/derivatives from human origin.
- No use of tissues/derivatives from animal origin.
- No use of materials from vegetal origin.
- No use of nano sized materials
- No use of nitrosamines.
- Conflict Minerals according to Regulation (EU) 2017/821 and defined by Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

For Etigam,
Sincerely,

E. Wolf
CEO