

Annex 2 Substitution of hazardous substances

Products must meet all chemicals of concern criteria¹:

1. LATEX – Does not contain latex in any material touched by patients or practitioners.
2. EUROPEAN UNION CANDIDATE LIST OF SUBSTANCES OF VERY HIGH CONCERN FOR AUTHORIZATION – All homogenous materials do not contain SVHCs above the concentration threshold of 0.1% w/w.

The Candidate List can be found at <https://echa.europa.eu/candidate-list-table>.

3. BISPHENOLS (Bisphenol A, BPA) – all homogeneous materials do not contain Bisphenol A and related structural/functional analogues above the concentration threshold of 0.1% w/w.

Structural/functional analogues include bisphenol AP, bisphenol AF, bisphenol B (BPB), bisphenol C, bisphenol C2, bisphenol E (BPE), bisphenol F (BPF), bisphenol G, bisphenol M, bisphenol S (BPS), bisphenol P, bisphenol PH, bisphenol TMC, bisphenol Z, and 4-cumylphenol (HPP) or Bisphenol A derived chemicals. Bisphenol A is on the Candidate List.

4. POLYVINYL CHLORIDE (PVC) – Does not contain Polyvinyl Chloride.
5. PHTHALATES – All homogenous materials do not contain phthalates listed on the Candidate List or in Annex XVII to REACH entry 51 and 52 above the concentration threshold of 0.1% w/w.

The Candidate List can be found at <https://echa.europa.eu/candidate-list-table>. Annex XVII to REACH entry 51 and 52 can be found at <https://echa.europa.eu/substances-restricted-under-reach>.

6. ANTIMICROBIAL AGENTS – Does not contain antimicrobial agents.

Microbes are viruses, bacteria, mycobacteria, yeast, fungi and bacterial spores etc. Antimicrobial agents include aldehydes, including OPA, quaternary ammonium compounds, biguanide (PHMB) and chlorhexidine. The list is not exhaustive.

¹ Any exemptions from the requirements will be detailed in the tender document for the relevant procurement. Exemptions may apply if the substance is included in a product for medical reasons, and in cases where market research indicates that there are no available products without these substances.