Assent University

EU MDR 2017/745 DECLARATION ACCEPTANCE CRITERIA

IMPORTANT: This guideline is for information purposes only and does not constitute legal advice. This guide is for communicating compliance with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices within the supply chain. The acceptance criteria below is for communicating the presence of substances as defined in section 10.4.1 of the regulation.

1. ON COMPANY LETTERHEAD.

a. Needs to indicate that the declaration/certificate is an official company release.

2. INCLUDES THE PROPER EU MEDICAL DEVICE REGULATION (MDR) LEGISLATIVE REFERENCE.

a. This indicates the supplier has some awareness of the legislation being inquired about. Actual legislation title: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

3. INCLUDES UNIQUE REFERENCE TO PARTS OR PRODUCTS BEING COVERED BY THE DECLARATION.

4. DECLARES COMPLIANCE STATUS.

a. States that it does not contain any substances as defined in section 10.4.1 of the regulation.

b. States that it does contain any substances as defined in section 10.4.1 of the regulation.

5. DECLARES SUBSTANCES PRESENT IF APPLICABLE.

a. If a part or parts contain a substance as defined in section 10.4.1, the declaration must include which substance(s) are present and be linked directly to the part or parts in which they are present.

6. SIGNED BY APPROPRIATE INDIVIDUAL.

a. Name, contact details and position must be included.

b. Must be an employee of the company issuing the declaration.

c. Position/job title should indicate a degree of familiarity with materials or product adequate to stating compliance status.

   i. e.g. Engineering, Quality, Materials, Compliance Manager.

7. DATE OF REFERENCE.

a. The substances referenced in section 10.4.1 refer to regulatory substance lists that are typically updated every six months. Therefore, the declaration must identify that it applies to the most recent additions on the applicable regulatory list and specify the date of the list.

   i. EU Classification, Labelling and Packaging (EC) No 1272/2008 for substances which are carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1A or 1B, and: https://echa.europa.eu/information-on-chemicals/annex-vi-to-clp.

   ii. EU REACH (EC) No 1907/2006 for substances having endocrine-disrupting properties. https://echa.europa.eu/candidate-list-table.

Assent

525 Coventry Road
Ottawa, ON, K1K 2C5
Canada

1 866 964 6931
info@assentcompliance.com
assentcompliance.com