



Metal Tubing Specialists

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Declaration of Substances Requiring Labeling, Justification, or Precautions per the EU Medical Device Regulation --Regulation (EU) 2017/745

Per Annex I, Chapter II, point 10.4.1 of Regulation (EU) 2017/745, medical devices using Accumetrics Limited's stainless steel alloy tubular parts may require labeling and justification because the parts contain residual cobalt above 0.1% by weight.

Per Annex I, Chapter III, point 23.4 of Regulation (EU) 2017/745, medical devices using Accumetrics Limited's stainless steel alloy tubular parts may require *instructions for use* precautions because the parts contain residual cobalt, a category 1B carcinogen.

Also, per Annex I, Chapter III, point 23.4 of Regulation (EU) 2017/745, medical devices using Accumetrics Limited's nickel alloy tubular parts may require *instructions for use* precautions because the parts contain metallic nickel, a recognized allergen.

Fred Even

A handwritten signature in black ink that reads "Fred Even". The signature is stylized with a cursive-like font.

Management Representative

09/21/2022

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