

RE: REACH Authorization

[Insert Date]

Dear [Insert Name],

Smiths Medical understands that a substance on the Candidate List of Substances for Authorization (also known as the Substances of Very High Concern (SVHC)) under the Regulation for Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH Regulation EC No. 1907/2006") is not subject to restriction under the REACH Regulation until it is added to Annex XIV of the REACH Regulation. Smiths Medical also notes that the Guidance on the REACH Regulation published by the European Chemicals Agency (section 1.5.2, Table 1) states that chemicals used in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC and Directive 2001/83/EC {Art. 2.5} are exempt from the authorization requirements under the REACH Regulation, and further that the Guidance (section 2.2.3.3) states that an application for authorization is not required for a medical device regulated by Directives 90/385/EEC, 93/42/EECor 98/79/EC {Art. 62(6)} unless the SVHC is on the Candidate list due to potential environmental harm. Smiths Medical's products do not contain any such SVHC. Smiths Medical is committed to complying with these regulations and also to the REACH Regulation as it applies to Smiths Medical's products.

Sincerely,

Smiths Medical ASD, Inc.