BFM GLOBAL LTD
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Beachhaven,
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New Zealand

31 JULY 2018

Declaration relating to

Seeflex Materials 040E, 040AS, 020E & 060ES

NOTE: This statement is made on the information provided to us by the material supplier and corresponds with our actual knowledge. BFM® Global uses Seeflex 040E, Seeflex 040AS, Seeflex 020E and Seeflex 060ES to manufacture our connectors, however, we cannot guarantee the suitability of the material for any given application and assume no liability in connection with the information provided below.

Leachable Substances:

To the best of our knowledge, BFM® Global's material suppliers do not use or intentionally incorporate the following agents into the Seeflex 040E, 040AS, 020E or 060ES that we use for production of our connectors.

- Bisphenol-A (BPA)
- Bis (2-ethylhexy) phthalate (DEPH)
- Dibutyl Phthalate (DBP)
- Benzyl Butyl Phthalate (BBP) or any other Phthalates)
- Cyanuric Acid
- Latex
- Melamine
- Nonylphenols
- Oleamide
- Silicone

TSE and BSE:

Seeflex 040E, Seeflex 040AS, Seeflex 020E and Seeflex 060ES are synthetic organic materials that do contain substances derived from tallow sources. Our suppliers have assured us that processing conditions used in the production of these tallow derivative products are in compliance with the minimum conditions described below for the processing of rendered fats listed in Annex XIII, Chapter XI of the EU Regulation 142/2011/EC, and the Notes for Guidance EMA/410/01 Rev 3.

Process Conditions: Regulation 142/2011/EC Annex XIII Chapter XI

A) Transesterification or hydrolysis at at least: 200˚C, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and esters); or

B) Saponification with NaOH 12 M (glycerol and soap) in a batch process at 95˚C for 3 hours, or in a continuous process at 140˚C, 2 bars (2,000 hPa) for 8 minutes; or

C) Hydrogenation at 160˚C at 12 bars (12,000 hPa) for 20 minutes.

These conditions are considered to be sufficient to inactivate BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy) transmitters. The conditions also meet the requirements of ISO 22442-1:2007 Annex C.5 regarding the processing of tallow derivatives used in medical devices.

Additionally, this tallow derivative product is compliant with the US Food and Drug Administration regulations regarding the use of prohibited cattle materials in food (21 CFR § 189.5) and cosmetics (21 CFR § 700.27), as prohibited cattle materials do not include tallow derivatives.

SIGNED ON BEHALF OF BFM GLOBAL LTD

BLAIR MCPHEAT
DIRECTOR