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Certification Médical-Santé

Paris, on April 9th, 2017

Subject: Tallow derivatives in packaging materials and in the processes of plastic materials transformation

Dear Madam, Dear Sir,

We would like to draw your attention on the fact that some materials, used for the packaging of medical devices, are likely to use tallow derivatives during their manufacturing process. Tallow is fat obtained from animal tissues including subcutaneous, abdominal and inter-muscular areas and bones.
Besides, we remind you that it is known that some plastic materials transformation processes may also imply the use of tallow derivatives.

If you are concerned by one of the above situations, your medical devices are considered medical devices incorporating a substance from animal origin and Essential Requirement 8.2 of Annex I of directive 93/42/EEC is applicable. As such, the associated risks should be managed in the risk management file(s) of the concerned medical device(s), by taking into account the nature of the contact with the patients, users and third parties[1].

However, with regards to Meddev 2.4/1 revision 9 guideline, we remind you that the classification rule n°17 of Annex IX of directive 93/42/EEC does not apply if your devices incorporate tallow derivatives.

Besides, we also draw your on attention on the fact that Regulation (EU) n°722/2012, related to devices manufactured utilising tissues of animal origin, specifically excludes:

- Medical devices which are not intended to come into contact with the human body or which are intended to come into contact with intact skin only.

- Tallow derivatives, processed under conditions at least as vigorous as those reminded below:
  - *Trans-esterification or hydrolysis at not less than 200 °C for not less than 20 minutes under pressure (glycerol, fatty acids and fatty acid esters production),*
  - *Saponification with NaOH 12 M (glycerol and soap production)*
    - *Batch process: at not less than 95 °C for not less than 3 hours,*
    - *Continuous process: at not less than 140 °C, under pressure for not less than 8 minutes or equivalent,*
  - *Distillation at 200 °C.*

[1] European Harmonized standard EN ISO 22442-1 : 2007 and EN ISO 22442-1 : 2015 (not yet harmonized)

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Thus, if your medical devices are concerned by the presence of tallow derivatives and are intended to come into contact with the human body or with non-intact skin, we kindly invite you to contact your supplier(s) of packaging materials and of plastic materials in order to obtain a certificate that should include all necessary information on the process parameters to allow you to conclude on the applicability (or not) of Regulation (EU) n°722/2012 and, if need be, to conduct all associated regulatory activities.

Through this communication, we also intend to inform you that, starting on May 15th, 2018, this (these) certificate(s) could be reviewed by LNE/G-MED during on-site audits of your quality management system and will also have to be provided in the EC type examination and EC design examination files.

We remain available for any further information you may require on this topic,

Yours faithfully,

Cécile Vaugelade
G-MED Certification Division Manager