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To whom it may concern

CONFIRMATION: TSE/BSE – CERTIFICATE OF ORIGIN

We herewith confirm that the plastic materials used in the manufacture of our medical devices

Omnifix®-F Luer Duo
Omnifix®-F Luer Lock Solo
Omnifix®-F Luer Solo
Omnifix®-F Slip
Omnifix®-H Luer Solo
Omnifix® Enteral
Omnifix® Lock
Omnifix® Luer Duo
Omnifix® Luer Lock Duo
Omnifix® Luer Lock Solo
Omnifix® Luer Solo
Omnifix® Slip
Omnifix®

do not contain tissues or cells of animal origin or their derivatives as referred to in regulation (EU) No 722/2012.

If additives derived from animal sources (tallow) are used in the production of these plastic materials they undergo a series of rigorous process steps (temperature > 200 °C, time > 20 min., under pressure) which according to European Pharmacopoeia 5th Edition, Chapter 5.2.8. "Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medical Products" are considered to be effective TSE inactivation processes.

Tallow derived materials used in this product fulfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMEA/410/01, rev. 3".

For and on behalf of

B. Braun Melsungen AG

i. A.

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