Carbon

Bovine Spongiform Encephalopathy (BSE) –
Compliance Declaration Statement – March 2020

The European Medicines Agency Regulation EMEA/410/01 Rev. 3 on Minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products, entered into force on July 1, 2011, and affects all materials that come into direct contact with the equipment used in manufacture of the medicinal product or that come in contact with the medical product and therefore have the potential for contamination.

Carbon and/or its manufacturing partners, to our knowledge, do not use directly or in-directly animal derived materials in the production of Carbon resins.

Parts manufactured with Carbon resins are considered as articles. These products/articles under normal and reasonable conditions of use, do not contain or come in contact with infective agents responsible for transmitting Transmissible Spongiform Encephalopathies (TSE), as defined in EMEA/410/01 Rev. 3.

The following list of Carbon resins DO NOT contain or come in contact with any infective agent per EMEA/410/01 Rev 3:

- PR 25
- RPU 70
- FPU 50
- EPU 40
- EPU 41
- EPU 42
- EPU 43
- EPU 44
- EPU 60
- CE 221
- EPX 82
- UMA 90
- MPU 100
- SIL 30
- DPR 10
- RPU 130

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