

Prevention of BSE/TSE risks: The quality strategy of INTEGRA Biosciences

INTEGRA Biosciences is committed to provide reliable, high-quality products which are safe and compliant with relevant regulations worldwide.

INTEGRA Biosciences consumables are produced from virgin materials using precise and consistent manufacturing techniques to ensure quality and excellent performance. **INTEGRA Biosciences** is committed to advance the use of recycled materials and bio-based plastics in the packaging of its consumables, wherever possible. Our product lots are traceable down to the corresponding raw material used and date produced. Our manufacturing process incorporates consistent in process inspection throughout all phases of fabrication and assembly. All consumables are produced in a controlled environment to ensure purity and cleanliness. **INTEGRA Biosciences** consumables produced under these conditions are contaminant free and consistent from lot to lot.

This document gives a statement regarding BSE / TSE and **INTEGRA Biosciences** consumable products

INTEGRA Biosciences implements strict quality standards and measures to ensure that its products meet the highest requirements, particularly with regard to the avoidance of animal ingredients and the risk of transmission of TSE/BSE (Transmissible Spongiform Encephalopathies/Bovine Spongiform Encephalopathy) agents.

Summary of the measures taken by INTEGRA Biosciences:

Product analysis: a thorough analysis of all substances and auxiliaries has been carried out to ensure that no animal components are present.

Certificates of conformity: **INTEGRA Biosciences** has contacted suppliers to obtain certificates of compliance to prove that the products are free of animal ingredients.

Creation of work and process instructions: Clear work, procedural and operational instructions were drawn up for the departments concerned to ensure that all measures in the regulated areas are complied with.

Minimising the TSE/BSE risk: **INTEGRA Biosciences** ensures that these measures minimise the risk of transmission of TSE/BSE pathogens and guarantee the safety of the products.

Future-oriented optimisation: **INTEGRA Biosciences** is committed to continuing to work actively on optimising product requirements in order to meet the high standards.

These proactive measures help to ensure that **INTEGRA Biosciences** not only fulfils regulatory requirements, but also sets the highest standards in terms of quality, safety and sustainability in the manufacture and development of its products.

INTEGRA Biosciences is not a manufacturer of medical devices, but the following regulations apply accordingly:

EU Directive 2003/32/EC

Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin.

EU Regulation 722/2012 EU

Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin.

The products listed in the table below are free from Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE).

These products do not contain raw materials or substances of animal origin. In addition, these products are not derived from specified risk materials as defined by either of the above regulations.

No ingredients of animal origin are used in the manufacturing process, nor do our products come into contact with animal products during storage or transport. The quality management system under which they are manufactured complies with ISO 9001.

Product article numbers	Product descriptions
153015	Filter 0.45 mm sterile
156608	Filter 0.20 mm sterile
3250, 3255	Small POPTOP Base and Large POPTOP Base
3805, 3808, 3815, 3818, 3413, 3714, 3715, 3416, 3717, 3718, 3403, 3704, 3705, 3406, 3707, 3708, 4401, 4402, 4411, 4412	GRIPTIPS for 2, 10, 12.5 and 20 µl handheld pipettes
6403 - 6405, 6453 - 6455, 6475, 6503 - 6505, 6553 - 6555, 6575	12.5 µl GRIPTIPS for benchtop platforms
3423, 3724, 3725, 3426, 3727, 3728, 3825, 3828, 4421, 4422	GRIPTIPS for 50, 100 and 125 µl handheld pipettes
6463 - 6465, 6563 - 6565	50 and 125µl GRIPTIPS for benchtop platforms
3433, 3734, 3735, 3483, 3784, 3785, 3835, 3633, 3934, 3935, 4431, 4432	GRIPTIPS for 200 and 300 µl handheld pipettes
6433 - 6435, 6485, 6533 - 6535, 6635, 6432	200 and 300 µl GRIPTIPS for benchtop platforms
3443, 3744, 3745, 3795, 3845, 3643, 3944, 3945, 4441, 4442	GRIPTIPS for 1000 and 1250 µl handheld pipettes
6443 - 6445, 6495, 6543 - 6545, 6643 - 6645, 6442	1250 µl GRIPTIPS for benchtop platforms
4455, 4454, 4453, 4451, 4456	GRIPTIPS for 5000 µl handheld pipettes
4304 - 4306, 4310 - 4312, 4320 - 4322, 4330 - 4332	Multichannel reagent reservoirs
4350 - 4357, 4360 - 4366	12 well reagent reservoirs
6301 - 6308, 6317 - 6318, 6327, 6328, 6337, 6338, 6347, 6348	Automation friendly reagent reservoirs
6351, 6352, 6361, 6362, 6371, 6372	Polypropylene reagent reservoirs
5722, 5724, 5742	VIAFILL Dispensing Cassettes
5100, 5101, 5110	WELLJET EasySnap™ dispensing cassettes
1401 - 1407, 1501 - 1507	Serological pipets

1 Signature

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If you require further information or a more detailed explanation on a specific aspect, please do not hesitate to contact us!

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