

Certificate of Quality

Product number: 800020 / 800030
Lot number: 20140328
Product description: **Bioswisstec Cell scraper**, L= 22.5cm / 29.5cm

Processed Material

Granulate yellow Highest grade, virgin raw material
 - Free of stripping agents, softeners or heavy metals
 Polyethylene (PE) Does not contain substances of animal origin and is therefore free of TSE/6SE
 Highest grade, virgin raw material
 - Free of stripping agents, softeners or heavy metals
 - Does not contain substances of animal origin and is therefore free of TSE/BSE
 - Fulfils the criteria of USP class VI medical devices according to directive 93/42

Quality Management System

Clean Room Conditions Manufactured in clean room conditions, in accordance with the valid specifications.
 GMP Production cGMP oriented
 ISO Certification Certified ISO 9001:2008
 scope no: 14
 issued on: 2014-07-15
 validity date: 2017-07-14
 registration number: CH-12483

Biological Safety

Cytotoxicity Representative product was tested according to ISO 10993-5, USP 31 and has been shown to be non-cytotoxic
 DNA/RNA Free of detectable DNA/RNA and ATP
 DNase/RNase Free of detectable Dnase/Rnase
 Level of Endotoxins <0,06 EU/ml Free of detectable endotoxins (pyrogens)
 Representative product test with Limulus Amoebocyte Lysate test (LAL) according to the guidelines FDA 12/87, Ph. Eur. and USP. Detection limit: <0,06 EU/ml
 Sterility Product was sterilized, process is validated according to ISO 11137

Functional Attribute

Leak Tightness of Pouch Lot In accordance with the valid specifications
 Number 8-digit lot number printed on each product pouch and case label
 Peel-off Joint Tear off strength in accordance with the valid specifications
 Scraper Blade Width of scraper blade and ease of twist are in accordance with the valid specifications

Visual Attribute

Integrity Product samples were visually inspected in accordance with the valid specifications

Quantitative Quality

Packaging Quantity Quantity in accordance with the specifications

Sterilization

Single Use Product intended for single use only
 Sterilization Sterilized by radiation, process is validated according to ISO 11137

Component Material

Colorings	Free from heavy metals
Packaging Materials	Free from heavy metals
Single Packaging Pipettes	Paper/plastic wrapping

Storage and Warehousing

Expiration Time	Expiration time (EXP) 6 years from date of manufacture
Product Packaging	Quality and quantity check passed at time of delivery ex works Bioswisstec.
Storage Recommendation	Relative humidity max.: 50 - 60 % Temperature: 10 - 30 °C (50 - 86 °F) Do not expose to direct sunlight

Bioswisstec AG



Delf Heger
Quality Control Manager

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