



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 28-Apr-2017

NL26S11859111-1-1

This is to certify that Synergy Health, location Etten-Leur has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2015 Sterilisation of Health Care Products
EN ISO 9001:2008 Quality Management System
EN ISO 13485:2012 Quality System - Medical Devices

ITW Contamination Control B.V.
Saffierlaan 5
2132 VZ HOOFFDORP
NETHERLANDS

Order Information

Account Number:	105405
Synergy Health Sales Part Reference:	1076697
Customer Reference Number:	TX3211, Lot#170861, Expiry Date: (200200)
Product Description:	GS6000 Val. Instr. Med. Art 25-45 kGy, Dens 0,1-0,14
Quantity Received:	6
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	TX3211, Lot#170861, Expiry Date: (200200)

Irradiation Data

Date and Time of Irradiation:	26-APR-2017 21:13
Calculated Minimum Dose kGy:	26.0
Calculated Maximum Dose kGy:	39.6

Irradiation Release Authorised By Synergy Health Ede B.V. location Etten-Leur.

Processing Site: Soeverijnstraat 2, , ETTEN-LEUR, 4879 NN Phone No: +31 (0) 765041055

Registered Office: Postbus 109, 3100 AC SCHIEDAM, NETHERLANDS

VAT Number: NL006847146B01



Product Number: TX3211
Lot Number: 170861
Manufactured Date: 5/2/2017

CERTIFICATE OF COMPLIANCE

Texwipe certifies that the above product/material listed conforms to procedures and specifications according to Texwipe Operating Procedures and Work Instructions.

Texwipe certifies that the lot number provided under this Certificate has been inspected and tested, in accordance with Texwipe specifications.

THE FOLLOWING INFORMATION IS PRODUCT SPECIFIC

Sterile Products: Texwipe certifies that the lot number provided under this certificate has been gamma irradiated to a sterility assurance level of 10^{-6} according to the guidelines of Association for the Advancement of Medical Instrumentation.

Sterile Alcohol and Sterile Pre-wetted Wipers: Texwipe certifies that the lot number provided under this certificate has been filled with a final concentration as listed in the Certificate of Analysis above and USP Purified Water solution filtered through 0.2 micron filters.

Approved By:

Christopher R. Creasy

Date: May 02, 2017

Time: 7:51:52 AM EST

TEX-QA-REC-8.2-001 Rev000

Confidential

Texwipe
No. 4660, Pang Jin Road • Wujiang Economic Development Zone • Wujiang, Jiangsu, China 215200 • Tel: +86.512.63033700
• Fax: +86.512.63033500