

Change Announcement



January 2021

Certificate of Analysis (CoA) and Certificate of Processing/Irradiation (CoP/Col) Changes

Products affected: All products that have a CoA and/or a CoP/Col

Effective Date: January 20, 2021

Updates:

- CoPs/Cols:**
 - Product Description will be added to all CoPs/Cols
 - Company's global addresses are updated at the bottom of the page
 - Manufacturing location is added to the header (Effective Feb 8)

CoAs:

- Product Description will be moved to be the first item below the document title
- The product description will be updated to reflect the product brand name
- Company's global addresses are updated at the bottom of the page
- Manufacturing location is added to the header (Effective Feb 8)

Current CoP/Col

Updated CoP/Col

Product Number: TX3265
Lot Number: 203504
Manufactured Date: 8/25/2020
Irradiation Date: 9/10/2020

Certificate of Processing / Certificate of Irradiation

Expiration Date			
Test	Specification	Units	Result
Expiration Date	Month (#). Year (####)	Date	8.2022

Irradiation Dose				
Test	Specification	Units	Result	Pass/Fail
Minimum Dose	16	kGy	22.5000	Pass
Maximum Dose	40	kGy	34.8000	Pass

Irradiator Location	
Irradiator Name	Location
Sterigenics	Charlotte, NC

Approved By: *Christopher R. Creasy* Date: August 26, 2020
Time: 12:30:23 PM EST

TEX-QA-REC-8.2-001 Rev000 Confidential
Texwipe 1210 South Park Drive • Kernersville, NC 27284 • Tel: 800-839-9473 • Fax: 338-998-2297

Product Number: TX3270
Lot Number: 201604
Manufactured Date: 4/10/2020
Irradiation Date: 4/21/2020
Manufacturing Location: USA

Certificate of Processing / Certificate of Irradiation

Product Description: Sterile 70% Isopropanol, 16 oz (473 ml) spray bottle

Expiration Date			
Test	Specification	Units	Result
Expiration Date	Month (#). Year (####)	Date	4.2022

Irradiation Dose				
Test	Specification	Units	Result	Pass/Fail
Minimum Dose	16	kGy	22.3000	Pass
Maximum Dose	40	kGy	30.8000	Pass

Irradiator Location	
Irradiator Name	Location
Sterigenics	Charlotte, NC

Approved By: *Christopher R. Creasy* Date: January 18, 2021
Time: 1:42:42 PM EST

TEX-QA-REC-8.2-001 Rev000 Confidential

Americas: Texwipe, 1210 South Park Drive, Kernersville, NC 27284, USA
Europe/Middle East/Africa: ITW Contamination Control, Battenhall 5, United States
Asia/Australia/Pacific Rim: Texwipe, 4, Circuit Street, SEPC, L1P L, Barrio Diezmo, Cabuyao, Laguna, Philippines, 4025
China: Texwipe, No.4660, Pang Jin Road, Wuliang Economic & Technological Development Zone, Suzhou, Jiangsu, China



Change Announcement



Current CoA

Updated CoA

Texwipe
An ITW Company

Product Number: TX3255
Lot Number: 203504
Manufactured Date: 8/25/2020

Certificate of Analysis

Bacterial Endotoxins		
Test	Specification	Units
Endotoxin	≤0.25 EU/mL	EU/mL

Chemical		
Test	Specification	Units
Appearance	Clear, Colorless Liquid	Not Applicable
Limit of Non-Volatile Residues	Does not exceed 2.5 mg/ 50mL	mg
Odor	Characteristic EtOH	Not Applicable
Specific Gravity @ 20° C/ 20° C	0.869-0.877	Not Applicable
Volume % v/v	Ethyl Alcohol 67%-73%	Percent

Expiration Date		
Test	Specification	Units
Expiration Date	Month (M), Year (####)	Date

Product Description		
Test	Specification	Units
Product Description	32 fluid ounce trigger spray	Not Applicable

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 sterilized 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 filtered through 0.2 micron filters.

Approved By: Date: August
Christopher R. Creasy Time: 3:34

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Texwipe
1210 South Park Drive • Kernersville, NC 27284 • Tel: 800-839-9473 • Fax: 336-996-2297

Texwipe
An ITW Company

Product Number: TX3255
Lot Number: 201604
Manufactured Date: 4/17/2020
Manufacturing Location: USA

Certificate of Analysis

Product Description	
Test	Specification
Product Description	Sterile 70% Denatured Ethanol, 32 oz (946 ml) spray bottle

Bacterial Endotoxins			
Test	Specification	Units	Result
Endotoxin	≤0.25 EU/mL	EU/mL	0.1250

Chemical			
Test	Specification	Units	Result
Appearance	Clear, Colorless Liquid	Not Applicable	Pass
Limit of Non-Volatile Residues	Does not exceed 2.5 mg/ 50mL	mg	0.0000
Odor	Characteristic EtOH	Not Applicable	Pass
Specific Gravity @ 20° C/ 20° C	0.869-0.877	Not Applicable	0.8740
Volume % v/v	Ethyl Alcohol 67%-73%	Percent	Pass

Expiration Date			
Test	Specification	Units	Result
Expiration Date	Month (M), Year (####)	Date	4.2022

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 and USP Purified Water solution filtered through 0.2 micron filters.

Approved By: Date: January 18, 2021
Christopher R. Creasy Time: 1:20:47 PM EST

TEX-QA-REC-8.2-001 Rev000 **Confidential**

Americas Texwipe 1210 South Park Drive Kernersville, North Carolina 27284 United States Tel: +1 336-996-7045 Tel/Fax: 800-839-9473 E-mail: info@texwipe.com	Europe/Middle East/Africa Texwipe ITW Contamination Control Safferslaan 5 2132 VZ Hoofddorp The Netherlands Tel: +31-88-1307-410 E-mail: info@texwipe.com	Asia/Australia/Pacific Rim Texwipe 4, Circuit Street, SEPZ, L10P 1, Barrio Diezmo, Cabuyao, Laguna, Philippines, 4025 Tel: +65-9115-9496 E-mail: asia@texwipe.com	China Texwipe No.4660, Fang Jin Road, Wujiang Economic & Technological Development Zone, Suzhou, Jiangsu, China Tel: +86-512-6303-3700 E-mail: asia@texwipe.com
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There are NO changes to product components, specification or packaging materials.

