



## Kitemark™ Certificate

This is to certify that:

3M Company  
3M Health Care  
dba 3M Consumer Health Care  
2510 Conway Avenue  
St. Paul  
Minnesota  
55144  
USA

Holds Certificate Number:

KM 657624

In respect of:

**BS EN ISO 11138 Biological Indicators  
Sterilization of health care products. Biological indicators.**

This issues the right and licence to use the Kitemark in accordance with the Kitemark Terms and Conditions governing the use of the Kitemark, as may be updated from time to time by BSI Assurance UK Ltd (the "Conditions"). All defined terms in this Certificate shall have the same meaning as in the Conditions.

The use of the Kitemark is authorized in respect of the Product(s) detailed on this Certificate provided at or from the above address.

For and on behalf of BSI:

Frank Lee, Product Certification Technical and Compliance Director

First Issued: 2016-10-03

Latest Issue: 2022-02-24

Effective Date: 2022-03-01

Expiry Date: 2025-02-28

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...making excellence a habit.™

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To check its validity telephone +44 (0) 345 080 9000. An electronic certificate can be authenticated [online](#).

BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A member of BSI Group of Companies.

# Kitemark™ Certificate

No. KM 657624

**BS EN ISO 11138-1:2017 - Sterilization of health care products. Biological indicators. General requirements**

**BS EN ISO 11138-3:2017 - Sterilization of health care products. Biological indicators for moist heat sterilization processes.**

<b>Models:</b>	<b>1262 3M Attest™</b>	Biological Indicator for steam sterilization.	
	<b>1262-S 3M Attest™</b>	Biological Indicator for life science and pharmaceutical steam sterilization processes.	
	<b>1292 3M Attest™</b>	Rapid Readout Biological Indicator for steam sterilization.	
	<b>1292E 3M Attest™</b>	Rapid Readout Biological Indicator for steam sterilization.	
	<b>1292-S 3M Attest™</b>	Rapid Readout Biological Indicator for industrial steam sterilization processes.	
<b>Description:</b>	Biological Indicators for steam sterilization process, designed to detect the presence of <i>Geobacillus stearothermophilus</i> , by the change of colour. Sterilization process fails, when media changes from purple to yellow.  The Rapid Readout BIs have a quicker readout, based on an enzymatic process for fluorescent colour change. The presence of fluorescent substrate is detected in the Attest™ Auto-reader, this indicates growth of bacteria and failure in the sterilization process.		
<b>Classification:</b>	Steam		
	<b>Stated Values</b>		
<b>Models</b>	<b>Temperature [°C]</b>	<b>D-Value</b>	<b>Incubation time</b>
<b>1262</b>	121°C	1.5 - 3 min	48 hours
<b>1262-S</b>	121°C	1.5 - 3 min	48 hours
<b>1292</b>	121°C	1.5 - 3 min	3 hours
<b>1292E</b>	121°C	1.5 - 4 min	3 hours
<b>1292-S</b>	121°C	1.5 - 2.5 min	3 hours

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No. KM 657624

**BS EN ISO 11138-1:2017** - **Sterilization of health care products. Biological indicators** (continued).

**BS EN ISO 11138-2:2017** - **Sterilization of health care products. Biological indicators for ethylene oxide sterilization processes**

<b>Models:</b>	<b>1264 3M Attest™</b>	Biological Indicator for ethylene oxide sterilization.
	<b>1264-S 3M Attest™</b>	Biological Indicator for life science and pharmaceutical ethylene oxide sterilization processes.
	<b>1294 3M Attest™</b>	Rapid Readout Biological Indicator for ethylene oxide Sterilization.
	<b>1294-S 3M Attest™</b>	Rapid Readout Biological Indicator for industrial ethylene oxide sterilization processes.

<b>Description:</b>	Biological Indicators for ethylene oxide (EO) sterilization process, designed to detect the presence of <i>Bacillus atrophaeus</i> , by the change of colour. Sterilization process fails, when media changes from blue-green to yellow. The Rapid Readout BIs have additional enzymatic process readout for fluorescent change, detected by the companion Attest™ Auto-reader, this indicates growth of bacteria and failure in the sterilization process.
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<b>Classification:</b>	Ethylene Oxide
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Stated Values			
Models	Temperature [°C]	D-Value	Incubation time
<b>1264</b>	54°C	2.5– 5.8 min	48 hours
<b>1264-S</b>	54°C	2 - 4 min	48 hours
<b>1294</b>	54°C	2.5 - 5 min	4 hours
<b>1294-S</b>	54°C	2 - 4 min	4 hours

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**BS EN ISO 11138-1:2017 - Sterilization of health care products. Biological indicators (continued).**

**BS EN ISO 11138-3:2017 - Sterilization of health care products. Biological indicators for moist heat sterilization processes.**

<b>Model:</b>	<b>1492V 3M Attest™</b> Super Rapid Readout Biological Indicator for steam sterilization.		
<b>Description:</b>	Biological Indicators for steam sterilization process, designed to detect the presence of <i>Geobacillus stearothermophilus</i> . Sterilization process fails, when the presence of fluorescent substrate is detected in the Attest™ Auto-reader, this indicates growth of bacteria and failure in the sterilization process. Additional results can be obtained by longer incubation time and observation of change of media colour from purple to yellow.		
<b>Classification:</b>	Steam		
	<b>Stated Values</b>		
Model	<b>Temperature [°C]</b>	<b>D-Value (Lower Release Limit)</b>	<b>Incubation time</b>
<b>1492V</b>	132°C	0.17 min	24 mins
	135°C	0.13 min	24 mins

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