Ansell Healthcare Europe NV/SA
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OCTOBER 2026

Addendum to the EMEA Change Notification Letter Issued in March 2026: Case Label Template Update - Manufacturing & Expiry Format Change - Certificate of Analysis (CoA) / Certificate of Conformance (CoC) / Certificate of Irradiation (CoI) / Certificate of Processing (CoP) Format Template Change.

Product Scope: Kimtech™ branded products supplied with a Certificate of Analysis (CoA) or Certificate of Conformance (CoC).

Dear Valued Customer,

Following the Change Notification Letter issued in March 2026, we would like to provide an update on the implementation progress and confirm several important milestones relating to the case label template update, manufacturing and expiry date format changes, and certificate template enhancements.

Case Label Template Update

We are pleased to inform you that the implementation of the new case label format, including the addition of a second label on the shipper case, is progressing well.

For our cleanroom sterile and non-sterile glove portfolio, the new label format has been fully implemented for products manufactured from May 2026 onwards. These products have already entered our distribution network and are being shipped to Ansell local distribution centers across the region.

The implementation for the remaining product categories, including cleanroom apparel, cleanroom masks and laboratory gloves, will be completed in a phased approach by the end of 2026.

As our supply chain operates on a First-Expired, First-Out (FEFO) basis, customers may continue to receive products bearing the previous label format until existing inventory has been exhausted.

Manufacturing & Expiry Date Format Change

The update to the manufacturing and expiry date format has been implemented in conjunction with the case label template update. Consequently, the rollout timeline mirrors that outlined above, with implementation already in place for cleanroom gloves manufactured from May 2026 onwards and a phased deployment planned for the remaining product ranges through the end of the year.

Certificate Format Change

We are also pleased to share the new Certificate of Analysis (CoA) and Certificate of Conformance (CoC) templates applicable to Kimtech™ branded products.

The updated certificate formats will apply to products manufactured from **October 2026 onwards** and will be available through our online certificate portal from **early December 2026**.

These revised templates have been developed following a thorough review of customer feedback and are designed to improve clarity, usability and consistency of information.

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Important Note:

All testing methods mentioned have been reviewed to ensure they are reflective of our product specifications and compliant with the regulatory status of each of our products.

Site of Product Release (Global) – New

Following a comprehensive review of our quality processes, we have established a dedicated Scientific Quality Team to further strengthen oversight and support for our Scientific product portfolio. While operating within the Reno Quality Management System (QMS), this team is based in Malaysia and will assume global responsibility for product release activities across these categories.

As a consequence, you will see an address change on the new CoA and CoC:

- Current 'Site of Product Release (Global)': Ansell Healthcare Products LLC 2301 Robb Drive, Reno, Nevada, 89523, USA
- New 'Site of Product Release (Global)': Ansell Global Trading Center (Malaysia) Sdn. Bhd., Prima 6, Prima Avenue, Block 3512, Jalan Technokrat 6, 63000 Cyberjaya, Malaysia.

Important note:

There is one (1) exception to the above: our Kimtech™ Exam Gloves portfolio, which is primarily marketed in North America and selected APAC countries. Due to regulatory requirements, the Reno site details will continue to be referenced on the corresponding Certificates of Analysis (CoAs).

The key enhancements to the certificate updated format include:

- Increased fonts size and the document will expand across two (2) pages if required.
- At the top of the page, we have introduced a new section clearly mentioning the legal manufacturer and the product releasing details
- The product information section is now including all need information: Brand/Product Name/Product Style/Product Code(s)/Lot Number/Batch Numbers/Total Number Cases/Manufacturing Date (YYYY-MM)/Expiry Date (YYYY-MM)
- Only one (1) certificate will be issued by production lot and all batches within this lot will be listed

For more information, please consult the Annexes where we have included:

- A side-by-side detailed comparison 'Current vs New' for the Sterile and Non-Sterile Cleanroom Gloves (same principles are applicable to the other ranges therefore no side-by-side comparison is provided) can be accessed **HERE**.
- Samples of CoA's and CoC's in the new format are provided below as shown in Annex I Samples of CoA's & CoC's (updated format).
- For CoC's: please note that the new template format contains the same information as the current document.

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We trust these updates will further enhance the transparency and usability of our product documentation while supporting your quality and compliance requirements.

Should you have any questions regarding these changes, please do not hesitate to contact your local Ansell representative.

Thank you for your continued partnership and trust in Ansell and the Kimtech™ brand.

Yours Sincerely,

Fiona Zwinkels-Stalker
Senior Marketing Director, EMEA/APAC

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SYT-12345

CERTIFICATE OF ANALYSIS

Legal Manufacturer:

Ansell Healthcare Europe N.V. Riverside Business Park-Block J, Blvd International, 55 B-1070 Brussels, Belgium

Site of Product Release:

Ansell Global Trading Center (Malaysia) Sdn Bhd Prima 6, Prima Avenue, Block 3512 Jalan Teknokrat 6 63000 Cyberjaya, Malaysia

PRODUCT INFORMATION

Brand:	Kimtech™
Product Name:	Kimtech™ Purple Nitrile™ Gloves
Product Style:	Kimtech-KTGPUP
Product Code(s):	90625, 90626, 90627, 90629
Lot Number:	2605UY
Batch Numbers:	2605H631UY
Total Number of Cases:	836
Manufacturing Date (YYYY-MM):	2026-05
Expiration Date (YYYY-MM):	2031-04

PINHOLE & VISUAL INSPECTION DATA

		Visual Defects	
Test Criterion	**Watertight**	**Major**	**Minor**
Sample Size :	315	315	200
AQL Level* :	0.65	2.5	4.0
Failures Allowed per AQL Level :	3	11	11
Failures :	0	0	0
Inspection Results :	**ACCEPT**	**ACCEPT**	**ACCEPT**
Test Method(s):	Watertight: ASTM D5151, EN 374-2		

**AQL Level determined in accordance with ISO 2859-1 sampling procedures.*

PHYSICAL PROPERTIES & RESIDUAL POWDER DATA

	Physical Properties (Pre-Aging)				
	Tensile Strength (Mpa)	**Median Force at Break (Newtons)**	**Ultimate Elongation (%)**		**Resdiual Powder (mg/glove)**
Average:	42.44	15.84	575	**Average:**	0.06
Median:	42.30	15.80	578	**Median:**	0.06
Standard Deviation:	3.90	1.61	17.63	**Standard Deviation:**	N/A
Minimum:	15	9	500	**Maximum:**	2
Target:	21	11	550	**Target:**	1
Inspection Results:	**ACCEPT**	**ACCEPT**	**ACCEPT**	**Inspection Results:**	**ACCEPT**
Test Methods :	ASTM D412	EN 455-2	ASTM D412	ASTM D6124 & EN 455-3	

FINAL LOT DISPOSITION

ACCEPT

Reviewed & Approved By:	**QA Approver Name**
Title:	**Quality Assurance**
Date:	**17-Aug-2026**

For additional information contact us at certificates@ansell.com or visit us at www.ansell.com.

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Ansell Healthcare Products LLC 2301 Robb Drive, Reno Nevada, 89523	**Ansell Healthcare Europe N.V.** Riverside Business Park-Block J, Blvd International, 55 B-1070 Brussels, Belgium

Site of Product Release (Global):

Ansell Global Trading Center (Malaysia) Sdn Bhd Prima 6, Prima Avenue, Block 3512 Jalan Teknokrat 6 63000 Cyberjaya, Malaysia

PRODUCT INFORMATION

Brand:	Kimtech™
Product Name:	Kimtech™ G3 Sterile White Nitrile Cleanroom Gloves
Product Style:	Kimtech-KTG3WN1S
Product Code(s):	56889, 56891, 56894
Lot Number:	2507UY
Batch Numbers:	25070105UY, 25070112UY, 25070101UY, 25070113UY, 25070201UY
Total Number of Cases:	455
Manufacturing Date (YYYY-MM):	2025-07
Expiration Date (YYYY-MM):	2030-06

PHYSICAL TEST DATA

		Visual Defects			Physical Properties (Pre-Aging)	
Test Criterion	**Watertight**	**Major**	**Minor**	**Dimensions**	**Elongation (%)**	**Tensile (Mpa)**
Sample Size :	575	575	575	180	80	80
AQL Level* :	1.5	2.5	4.0	2.5	2.5	2.5
Failures Allowed per AQL Level :	14	22	32	9	4	4
Failures :	3	0	0	0	0	0
Inspection Results :	**ACCEPT**	**ACCEPT**	**ACCEPT**	**ACCEPT**	**ACCEPT**	**ACCEPT**
				Averages	**588**	**37**
Test Method(s):	Watertight: ASTM D5151, EN 455-1	Dimensions: ASTM D3577 or ASTM D6319 (Nitrile) or ASTM D3578 (NRL) and EN 455-2			Elongation and Tensile: ASTM D412	

**AQL Level determined in accordance with ISO 2859-1 sampling procedures.*

PARTICLE TEST DATA

Particle Size (µm)	Minimum	Maximum	Standard Deviation	Average Particles / cm^2
0.5 - 1.0	644	701	25	675
1.0 - 2.0	123	169	22	144
2.0 - 5.0	45	71	13	64
5.0 - 10.0	10	18	4	13
10.0 - 20.0	6	15	4	10
> 20	2	5	1	4
Total per Sample	138	163	11	152

Test Method : IEST-RP-CC005

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EXTRACTABLE ION CONTENT

	Anion Results						
Unit	Bromide Br^-	Chloride Cl^-	Fluoride F^-	Nitrate NO_3^-	Nitrite NO_2^-	Phosphate PO_4^{-3}	Sulfate SO_4^{-2}
µg/g glove	N/A	24.020	N/A	7.440	N/A	N/A	3.410
µg/cm^2	N/A	0.150	N/A	0.050	N/A	N/A	0.020
	Cation Results					Trace Element Results	
Unit	Ammonium NH_4^+	Calcium Ca^{+2}	Magnesium Mg^{+2}	Potassium K^+	Sodium Na^+	Zinc Zn	
µg/g glove	1.130	14.470	1.130	2.200	1.890	6.67	
µg/cm^2	0.010	0.090	0.010	0.010	0.010	0.04	

Test Method : IEST-RP-CC005

ENDOTOXIN TEST DATA

Parameter	Result	Unit
Test Result:	BD	Endotoxin Units/ device
Specification:	< 20	Endotoxin Units/ device

Detection Limit is ≤ 0.4 EU / device: BD = Below Detection Limit

A device is defined as 1 pair of gloves

Test Method: Limulus Amebocyte Lysate (LAL) Test: Kinetic Turbidimetric Technique

STERILITY DATA

This product conforms to standards for sterility per ISO 11137 with sterility assurance level (SAL) 10^{-6}. A Certificate of Irradiation or Processing is also available to assure that the product has received the specified radiation dosage.

FINAL LOT DISPOSITION

ACCEPT

Reviewed & Approved By:	QA Approver Name
Title:	Quality Assurance
Date:	17-Aug-2026

For sterile products, a Certificate of Irradiation or Processing is also available to assure that the product has received the specified radiation dosage.

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CERTIFICATE OF ANALYSIS

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Ansell Healthcare Products LLC 2301 Robb Drive, Reno Nevada, 89523	**Ansell Healthcare Europe N.V.** Riverside Business Park-Block J, Blvd International, 55 B-1070 Brussels, Belgium

Site of Product Release (Global):
Ansell Global Trading Center (Malaysia) Sdn Bhd Prima 6, Prima Avenue, Block 3512 Jalan Teknokrat 6 63000 Cyberjaya, Malaysia

PRODUCT INFORMATION

Brand:	Kimtech™
Product Name:	Kimtech™ G3 White Nitrile Gloves
Product Style:	Kimtech-KTG3WN2
Product Code(s):	56880, 56883
Lot Number:	2507UY
Batch Numbers:	25070301UY, 25070601UY, 25070901UY, 25071024UY
Total Number of Cases:	178
Manufacturing Date (YYYY-MM):	2025-07
Expiration Date (YYYY-MM):	2030-07

PHYSICAL TEST DATA

		Visual Defects			Physical Properties (Pre-Aging)	
Test Criterion	**Watertight**	**Major**	**Minor**	**Dimensions**	**Elongation (%)**	**Tensile (Mpa)**
Sample Size :	5595	5595	4905	800	540	540
AQL Level* :	1.5	2.5	4.0	2.5	2.5	2.5
Failures Allowed per AQL Level :	134	198	271	40	27	27
Failures :	6	0	0	0	0	0
Inspection Results :	ACCEPT	ACCEPT	ACCEPT	ACCEPT	ACCEPT	ACCEPT
				Averages	**582**	**45.6**
Test Method(s):	Watertight: ASTM D5151, EN 455-1	Dimensions: ASTM D3577 or ASTM D6319 (Nitrile) or ASTM D3578 (NRL) and EN 455-2			Elongation and Tensile: ASTM D412	

**AQL Level determined in accordance with ISO 2859-1 sampling procedures.*

PARTICLE TEST DATA

Particle Size (µm)	Minimum	Maximum	Standard Deviation	Average Particles / cm^2
0.5 - 1.0	528	830	70	730
1.0 - 2.0	57	182	33	108
2.0 - 5.0	8	66	17	28
5.0 - 10.0	1	8	2	4
10.0 - 20.0	0	5	1	2
> 20	0	2	0	1
Total per Sample	99	182	21	145

Test Method : IEST-RP-CC005

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EXTRACTABLE ION CONTENT

	Anion Results						
Unit	Bromide Br^-	Chloride Cl^-	Fluoride F^-	Nitrate NO_3^-	Nitrite NO_2^-	Phosphate PO_4^{-3}	Sulfate SO_4^{-2}
µg/g glove	N/A	19.280	N/A	8.300	N/A	N/A	1.950
µg/cm^2	N/A	0.120	N/A	0.050	N/A	N/A	0.010

	Cation Results					Trace Element Results
Unit	Ammonium NH_4^+	Calcium Ca^{+2}	Magnesium Mg^{+2}	Potassium K^+	Sodium Na^+	Zinc Zn
µg/g glove	1.270	14.790	1.370	2.210	2.530	6.69
µg/cm^2	0.010	0.090	0.010	0.010	0.020	0.04

Test Method : IEST-RP-CC005

FINAL LOT DISPOSITION

ACCEPT

Reviewed & Approved By: QA Approver Name

Title: Quality Assurance

Date: 17-Aug-2026

For sterile products, a Certificate of Irradiation or Processing is also available to assure that the product has received the specified radiation dosage.

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Site of Product Release (Global):

Ansell Global Trading Center (Malaysia) Sdn Bhd Prima 6, Prima Avenue, Block 3512 Jalan Teknokrat 6 63000 Cyberjaya, Malaysia

PRODUCT INFORMATION

Brand:	Kimtech™
Product Name:	Kimtech™ A5 Sterile Cleanroom Apparel
Product Style:	Kimtech-KTA5AS
Product Code(s):	88802, 88803
Size(s):	L, XL
Lot Number:	2507UQ
Batch Number(s):	250709X1UQ
Manufacturing Date (YYYY-MM):	2025-07
Expiration Date (YYYY-MM):	2030-07

Ansell certifies that the above product has been manufactured in accordance with Ansell product specifications. Through a system of in-process and lot inspections, we assure conformance to all requirements. This lot has met all acceptance criteria, has been approved for release by Ansell Quality Assurance, and is suitable for its intended use. The product meets all specified performance, safety, and quality requirements.

PHYSICAL AND PERFORMANCE PROPERTIES

Standard/Property	Test Method	Specification Target	Result
Particle Count (tested prior to sterilization)	Helmke Drum, IEST-RP-CC003	Category 1	Conforms
Sterility Assurance Level	ANSI/AAMI/ISO 11137	10^{-6}	Conforms
REACH Regulation	EC 1907/2006 Compliance Verification	No SVHC above 0.1% w/w per Annex XVII	Conforms
BSE/TSE	EMEA/410/01 Compliance Verification	No animal-derived components	Conforms

FINAL LOT DISPOSITION

ACCEPT

Reviewed & Approved By:	**QA Approver Name**
Title:	**Quality Assurance**
Date:	**17-Aug-2026**

For sterile products, a Certificate of Irradiation or Processing is also available to assure that the product has received the specified radiation dosage.

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Site of Product Release (Global):

Ansell Global Trading Center (Malaysia) Sdn Bhd Prima 6, Prima Avenue, Block 3512 Jalan Teknokrat 6 63000 Cyberjaya, Malaysia

PRODUCT INFORMATION

Brand:	Kimtech™
Product Name:	Kimtech™ M3 Sterile Face Masks
Product Style:	Kimtech-KTM3BE7S
Product Code(s):	62470
Size(s):	7IN
Lot Number:	TH20175205
Batch Number(s):	N/A
Manufacturing Date (YYYY-MM):	2022-01
Expiration Date (YYYY-MM):	2027-01

Ansell certifies that the above product has been manufactured in accordance with Ansell product specifications. Through a system of in-process and lot inspections, we assure conformance to all requirements. This lot has met all acceptance criteria, has been approved for release by Ansell Quality Assurance, and is suitable for its intended use. The product meets all specified performance, safety, and quality requirements.

PHYSICAL AND PERFORMANCE PROPERTIES

Standard/Property	Test Method	Specification Target	Result
Particle Count (tested prior to sterilization)	Helmke Drum, IEST-RP-CC003	Category 1	Conforms
Sterility Assurance Level	ANSI/AAMI/ISO 11137	10^{-6}	Conforms
REACH Regulation	EC 1907/2006 Compliance Verification	No SVHC above 0.1% w/w per Annex XVII	Conforms
BSE/TSE	EMEA/410/01 Compliance Verification	No animal-derived components	Conforms

FINAL LOT DISPOSITION

ACCEPT

Reviewed & Approved By:	**QA Approver Name**
Title:	**Quality Assurance**
Date:	**17-Aug-2026**

For sterile products, a Certificate of Irradiation or Processing is also available to assure that the product has received the specified radiation dosage.

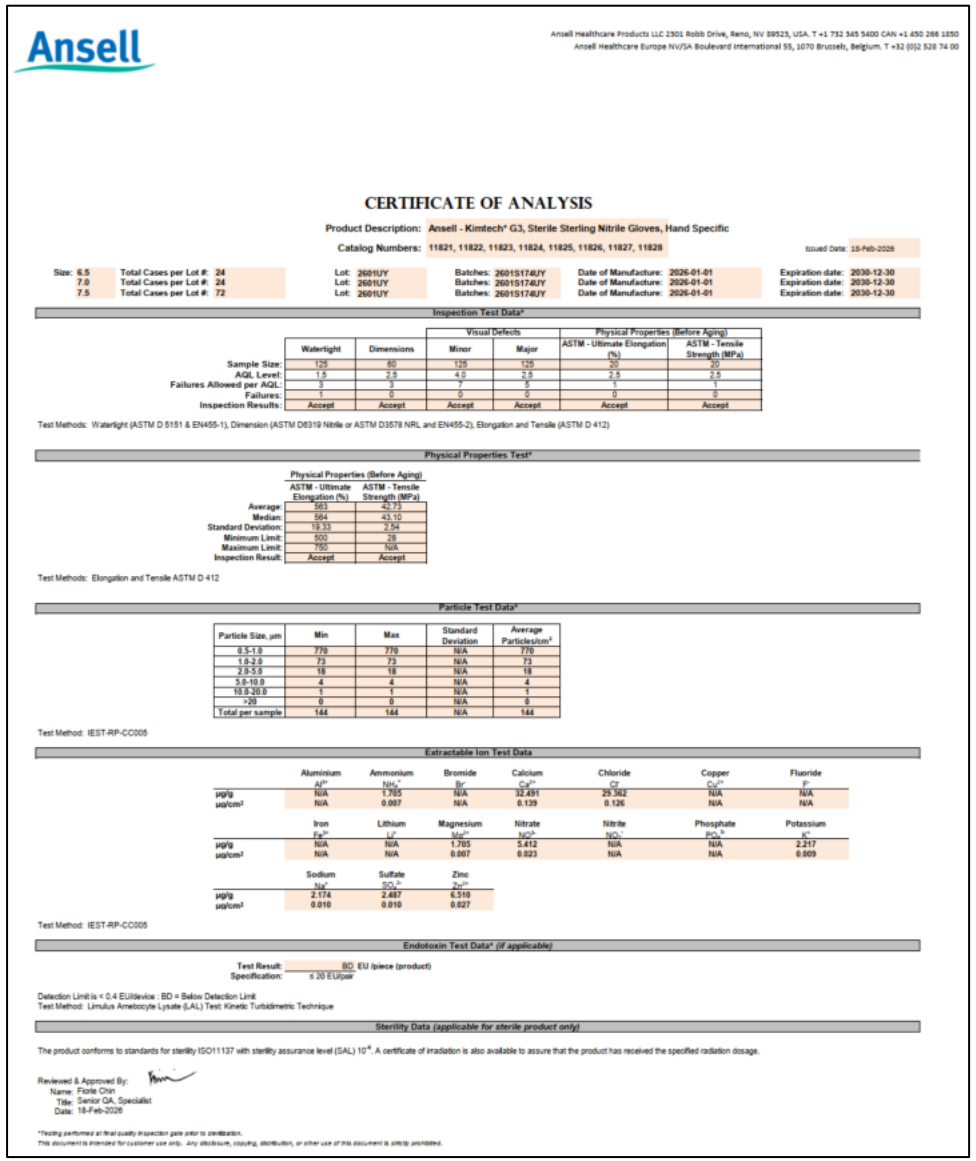
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Kimtech™ Sterile and Non-Sterile Cleanroom Gloves

Current CoA Template



Ansell

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Ansell Healthcare Europe NV/SA Boulevard International 55, 1070 Brussels, Belgium. T +32 (0)2 528 74 00

CERTIFICATE OF ANALYSIS

Product Description: Ansell - Kimtech* G3, Sterile Sterling Nitrile Gloves, Hand Specific

Catalog Numbers: 11821, 11822, 11823, 11824, 11825, 11826, 11827, 11828

Issued Date: 18-Feb-2026

Size: 6.5	Total Cases per Lot #: 24	Lot: 2601UY	Batches: 2601S174UY	Date of Manufacture: 2026-01-01	Expiration date: 2030-12-30
7.0	Total Cases per Lot #: 24	Lot: 2601UY	Batches: 2601S174UY	Date of Manufacture: 2026-01-01	Expiration date: 2030-12-30
7.5	Total Cases per Lot #: 72	Lot: 2601UY	Batches: 2601S174UY	Date of Manufacture: 2026-01-01	Expiration date: 2030-12-30

Inspection Test Data*

	Watertight	Dimensions	Visual Defects Minor	Visual Defects Major	Physical Properties (Before Aging) ASTM - Ultimate Elongation (%)	Physical Properties (Before Aging) ASTM - Tensile Strength (MPa)
Sample Size:	125	60	125	125	20	20
AQL Level:	1.5	2.5	4.0	2.5	2.5	2.5
Failures Allowed per AQL:	3	3	7	5	1	1
Failures:	1	0	0	0	0	0
Inspection Results:	Accept	Accept	Accept	Accept	Accept	Accept

Test Methods: Watertight (ASTM D 5151 & EN455-1), Dimension (ASTM D6319 Nitrile or ASTM D3578 NRL and EN455-2), Elongation and Tensile (ASTM D 412)

Physical Properties Test*

	Physical Properties (Before Aging) ASTM - Ultimate Elongation (%)	ASTM - Tensile Strength (MPa)
Average:	583	43.73
Median:	584	43.10
Standard Deviation:	19.33	2.54
Minimum Limit:	500	28
Maximum Limit:	750	N/A
Inspection Result:	Accept	Accept

Test Methods: Elongation and Tensile ASTM D 412

Particle Test Data*

Particle Size, µm	Min	Max	Standard Deviation	Average Particles/cm²
0.5-1.0	770	770	N/A	770
1.0-2.0	73	73	N/A	73
2.0-5.0	18	18	N/A	18
5.0-10.0	4	4	N/A	4
10.0-20.0	1	1	N/A	1
>20	0	0	N/A	0
Total per sample	144	144	N/A	144

Test Method: IEST-RP-CC005

Extractable Ion Test Data

	Aluminium Al^{3+}	Ammonium NH_4^+	Bromide Br^-	Calcium Ca^{2+}	Chloride Cl^-	Copper Cu^{2+}	Fluoride F^-
µg/g	N/A	1.705	N/A	32.451	29.382	N/A	N/A
µg/cm²	N/A	0.007	N/A	0.139	0.126	N/A	N/A

	Iron Fe^{3+}	Lithium Li^+	Magnesium Mg^{2+}	Nitrate NO_3^-	Nitrite NO_2^-	Phosphate PO_4^{3-}	Potassium K^+
µg/g	N/A	N/A	1.705	5.412	N/A	N/A	2.217
µg/cm²	N/A	N/A	0.007	0.023	N/A	N/A	0.009

	Sodium Na^+	Sulfate SO_4^{2-}	Zinc Zn^{2+}
µg/g	2.174	2.487	6.510
µg/cm²	0.010	0.010	0.027

Test Method: IEST-RP-CC005

Endotoxin Test Data* (if applicable)

Test Result: BD EU /piece (product)
Specification: ≤ 20 EU/pair

Detection Limit is < 0.4 EU/device ; BD = Below Detection Limit
Test Method: Limulus Amebocyte Lysate (LAL) Test: Kinetic Turbidimetric Technique

Sterility Data (applicable for sterile product only)

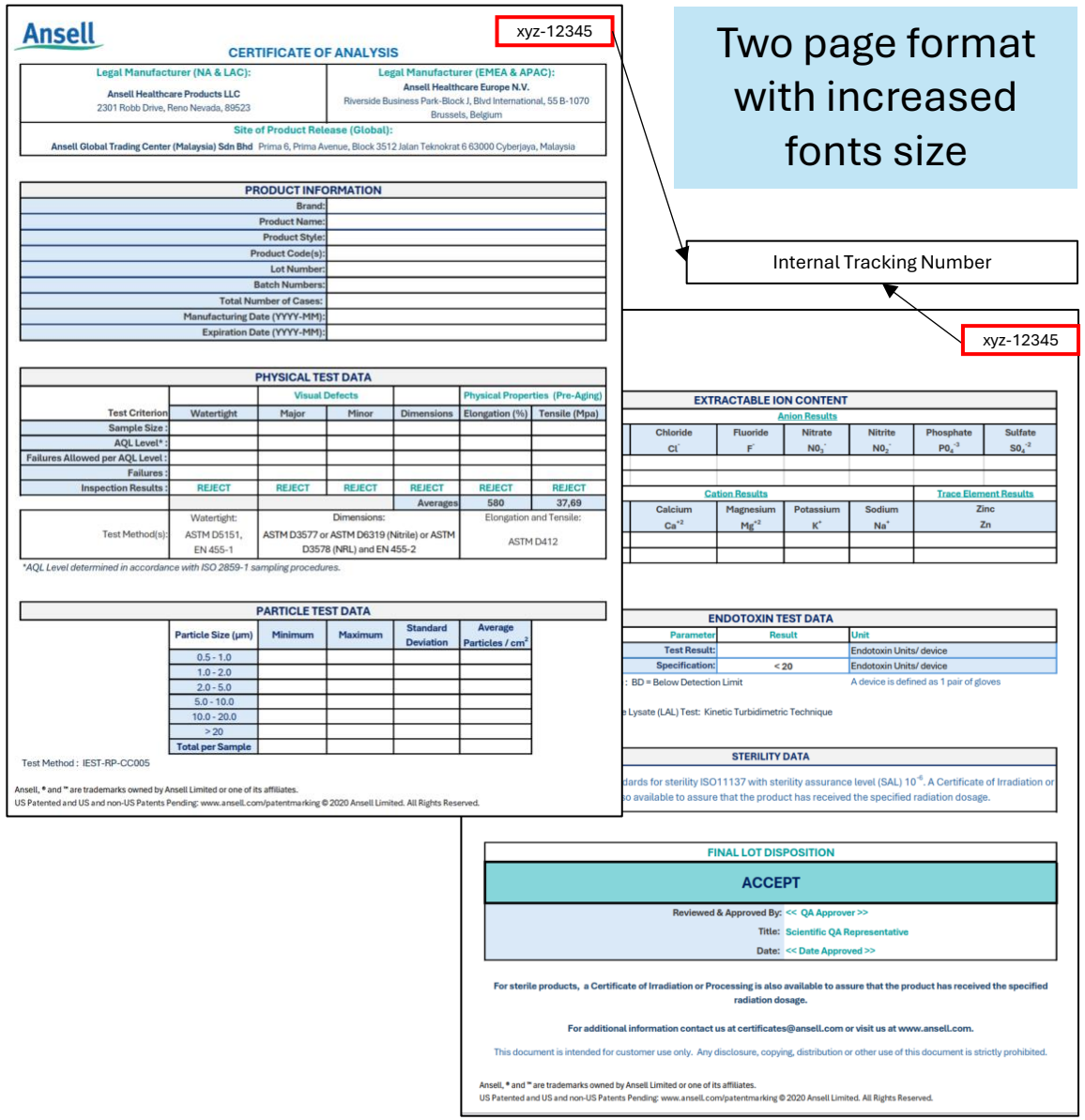
The product conforms to standards for sterility ISO11137 with sterility assurance level (SAL) 10^{-6}. A certificate of irradiation is also available to assure that the product has received the specified radiation dosage.

Reviewed & Approved By:
Name: Florie Chin
Title: Senior QA, Specialist
Date: 18-Feb-2026

*Testing performed at final quality inspection gate prior to sterilization.

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New CoA Template



Ansell

CERTIFICATE OF ANALYSIS

xyz-12345

Legal Manufacturer (NA & LAC):	Legal Manufacturer (EMEA & APAC):
Ansell Healthcare Products LLC 2301 Robb Drive, Reno Nevada, 89523	Ansell Healthcare Europe N.V. Riverside Business Park-Block J, Blvd International, 55 B-1070 Brussels, Belgium

Site of Product Release (Global):
Ansell Global Trading Center (Malaysia) Sdn Bhd Prima 6, Prima Avenue, Block 3512 Jalan Teknokrat 6 63000 Cyberjaya, Malaysia

PRODUCT INFORMATION

Brand:	
Product Name:	
Product Style:	
Product Code(s):	
Lot Number:	
Batch Numbers:	
Total Number of Cases:	
Manufacturing Date (YYYY-MM):	
Expiration Date (YYYY-MM):	

PHYSICAL TEST DATA

Test Criterion	Watertight	Visual Defects Major	Visual Defects Minor	Dimensions	Physical Properties (Pre-Aging) Elongation (%)	Physical Properties (Pre-Aging) Tensile (Mpa)
Sample Size :						
AQL Level* :						
Failures Allowed per AQL Level :						
Failures :						
Inspection Results :	REJECT	REJECT	REJECT	REJECT	REJECT	REJECT
				Averages	580	37,69
Test Method(s):	Watertight: ASTM D5151, EN 455-1	Dimensions: ASTM D3577 or ASTM D6319 (Nitrile) or ASTM D3578 (NRL) and EN 455-2			Elongation and Tensile: ASTM D412	

*AQL Level determined in accordance with ISO 2859-1 sampling procedures.

PARTICLE TEST DATA

Particle Size (µm)	Minimum	Maximum	Standard Deviation	Average Particles / cm²
0.5 - 1.0				
1.0 - 2.0				
2.0 - 5.0				
5.0 - 10.0				
10.0 - 20.0				
> 20				
Total per Sample				

Test Method : IEST-RP-CC005

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Two page format with increased fonts size

Internal Tracking Number

xyz-12345

EXTRACTABLE ION CONTENT

Anion Results

Chloride Cl^-	Fluoride F^-	Nitrate NO_3^-	Nitrite NO_2^-	Phosphate PO_4^{-3}	Sulfate SO_4^{-2}

Cation Results

Calcium Ca^{+2}	Magnesium Mg^{+2}	Potassium K^+	Sodium Na^+

Trace Element Results

Zinc Zn

ENDOTOXIN TEST DATA

Parameter	Result	Unit
Test Result:		Endotoxin Units/ device
Specification:	< 20	Endotoxin Units/ device

: BD = Below Detection Limit

A device is defined as 1 pair of gloves

e Lysate (LAL) Test: Kinetic Turbidimetric Technique

STERILITY DATA

dards for sterility ISO11137 with sterility assurance level (SAL) 10^{-6}. A Certificate of Irradiation or so available to assure that the product has received the specified radiation dosage.

FINAL LOT DISPOSITION

ACCEPT

Reviewed & Approved By: << QA Approver >>
Title: Scientific QA Representative
Date: << Date Approved >>

For sterile products, a Certificate of Irradiation or Processing is also available to assure that the product has received the specified radiation dosage.

For additional information contact us at certificates@ansell.com or visit us at www.ansell.com.

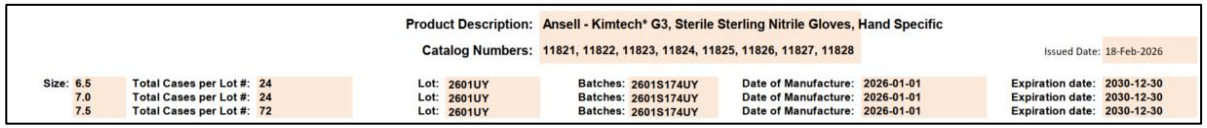
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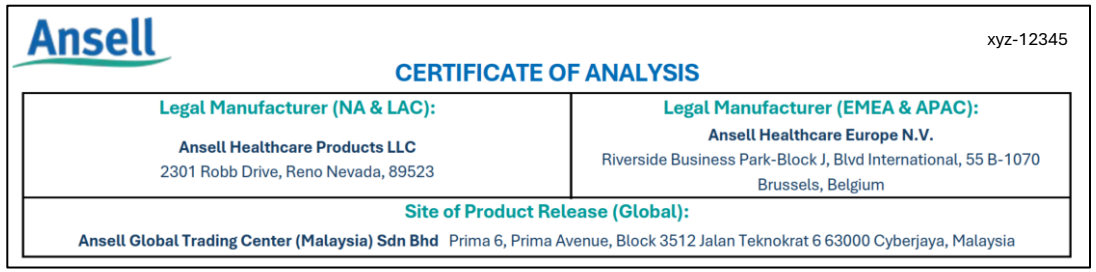
Kimtech™ Sterile and Non-Sterile Cleanroom Gloves

Current CoA Template



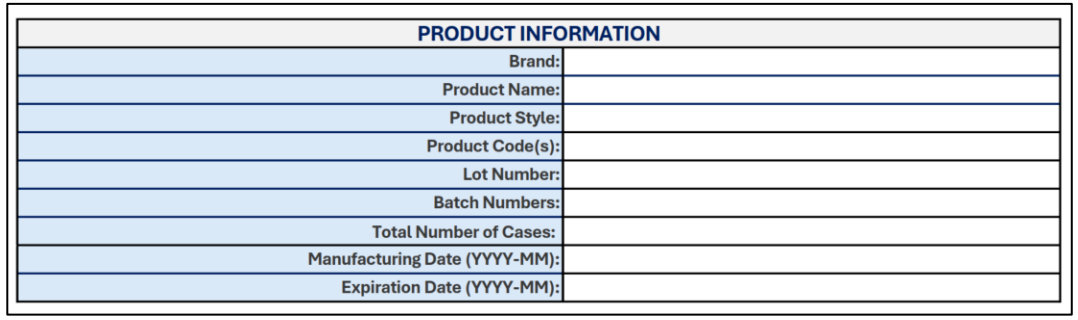


New CoA Template



Information is now organized in a logical way, indicating:

- The Legal Manufacturer(s)
- The site of Product Release



Complete and clear product information including:

- Brand/Product Name/Product Style/Product(s)…
- Batch Numbers : list of all batches included in the lot
- Total Number of Cases : gives visibility of all cases produced within this lot

Kimtech Sterile and non-sterile Cleanroom Gloves

Current CoA Template

Inspection Test Data*

			Visual Defects		Physical Properties (Before Aging)	
	Watertight	Dimensions	Minor	Major	ASTM - Ultimate Elongation (%)	ASTM - Tensile Strength (MPa)
Sample Size:	125	60	125	125	20	20
AQL Level:	1.5	2.5	4.0	2.5	2.5	2.5
Failures Allowed per AQL:	3	3	7	5	1	1
Failures:	1	0	0	0	0	0
Inspection Results:	Accept	Accept	Accept	Accept	Accept	Accept

Test Methods: Watertight (ASTM D 5151 & EN455-1), Dimension (ASTM D6319 Nitrile or ASTM D3578 NRL and EN455-2), Elongation and Tensile (ASTM D 412)

Physical Properties Test*

	Physical Properties (Before Aging)	
	ASTM - Ultimate Elongation (%)	ASTM - Tensile Strength (MPa)
Average:	563	42.73
Median:	564	43.10
Standard Deviation:	19.33	2.54
Minimum Limit:	500	28
Maximum Limit:	750	N/A
Inspection Result:	Accept	Accept

Test Methods: Elongation and Tensile ASTM D 412

New CoA Template

PHYSICAL TEST DATA

		Visual Defects			Physical Properties (Pre-Aging)	
Test Criterion	Watertight	Major	Minor	Dimensions	Elongation (%)	Tensile (Mpa)
Sample Size :						
AQL Level* :						
Failures Allowed per AQL Level :						
Failures :						
Inspection Results :	REJECT	REJECT	REJECT	REJECT	REJECT	REJECT
				Averages	580	37,69
Test Method(s):	Watertight: ASTM D5151, EN 455-1	Dimensions: ASTM D3577 or ASTM D6319 (Nitrile) or ASTM D3578 (NRL) and EN 455-2			Elongation and Tensile: ASTM D412	

**AQL Level determined in accordance with ISO 2859-1 sampling procedures.*

The 2 sections ‘Inspection Test Data’ and ‘Physical Properties Test’ have been merged into 1 section named ‘PHYSICAL TEST DATA’.

Each standard/test method used is clearly mentioned and lined up with each sub-section of the table.

Elongation/Tensile : only the first set of data previously shared in the ‘Inspection Test Data’ has been retained with the addition of the ‘Average’ results. This lines up with the level of information shared in the Kimtech legacy format.

Kimtech Sterile and non-sterile Cleanroom Gloves

Current CoA Template

Particle Test Data*

Particle Size, µm	Min	Max	Standard Deviation	Average Particles/cm²
0.5-1.0	770	770	N/A	770
1.0-2.0	73	73	N/A	73
2.0-5.0	18	18	N/A	18
5.0-10.0	4	4	N/A	4
10.0-20.0	1	1	N/A	1
>20	0	0	N/A	0
Total per sample	144	144	N/A	144

Test Method: IEST-RP-CC005

Extractable Ion Test Data

	Aluminium Al^{3+}	Ammonium NH_4^+	Bromide Br^-	Calcium Ca^{2+}	Chloride Cl^-	Copper Cu^{2+}	Fluoride F^-
µg/g	N/A	1.705	N/A	32.491	29.362	N/A	N/A
µg/cm²	N/A	0.007	N/A	0.139	0.126	N/A	N/A

	Iron Fe^{3+}	Lithium Li^+	Magnesium Mg^{2+}	Nitrate NO^{3-}	Nitrite NO_2^-	Phosphate PO_4^{3-}	Potassium K^+
µg/g	N/A	N/A	1.705	5.412	N/A	N/A	2.217
µg/cm²	N/A	N/A	0.007	0.023	N/A	N/A	0.009

	Sodium Na^+	Sulfate SO_4^{2-}	Zinc Zn^{2+}
µg/g	2.174	2.487	6.510
µg/cm²	0.010	0.010	0.027

Test Method: IEST-RP-CC005

Endotoxin Test Data* ***(if applicable)***

Test Result: BD **EU /piece (product)**
Specification: ≤ 20 EU/pair

Detection Limit is < 0.4 EU/device : BD = Below Detection Limit
Test Method: Limulus Amebocyte Lysate (LAL) Test: Kinetic Turbidimetric Technique

Sterility Data ***(applicable for sterile product only)***

The product conforms to standards for sterility ISO11137 with sterility assurance level (SAL) 10^{-6}. A certificate of irradiation is also available to assure that the product has received the specified radiation dosage.

New CoA Template

PARTICLE TEST DATA

Particle Size (µm)	Minimum	Maximum	Standard Deviation	Average Particles / cm²
0.5 - 1.0				
1.0 - 2.0				
2.0 - 5.0				
5.0 - 10.0				
10.0 - 20.0				
> 20				
Total per Sample				

Test Method : IEST-RP-CC005

EXTRACTABLE ION CONTENT

	Anion Results						
Unit	Bromide Br^-	Chloride Cl^-	Fluoride F^-	Nitrate NO_3^-	Nitrite NO_2^-	Phosphate PO_4^{-3}	Sulfate SO_4^{-2}
µg/g glove							
µg/cm²							

	Cation Results					Trace Element Results
Unit	Ammonium NH_4^+	Calcium Ca^{+2}	Magnesium Mg^{+2}	Potassium K^+	Sodium Na^+	Zinc Zn
µg/g glove						
µg/cm²						

Test Method : IEST-RP-CC005

ENDOTOXIN TEST DATA

Parameter	Result	Unit
Test Result:		Endotoxin Units/ device
Specification:	< 20	Endotoxin Units/ device

Detection Limit is ≤ 0.4 EU/device : BD = Below Detection Limit

A device is defined as 1 pair of gloves

Test Method : Limulus Amebocyte Lysate (LAL) Test: Kinetic Turbidimetric Technique

STERILITY DATA

This product conforms to standards for sterility ISO11137 with sterility assurance level (SAL) 10^{-6}. A Certificate of Irradiation or Processing is also available to assure that the product has received the specified radiation dosage.

No change to these sections just a new lay out. Endotoxin and sterility data only applies to sterile products

Kimtech™ Sterile and Non-Sterile Cleanroom Gloves

Current CoA Template

Reviewed & Approved By:
Name: Fiorie Chin
Title: Senior QA, Specialist
Date: 18-Feb-2026

**Testing performed at final quality inspection gate prior to sterilization.*
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New CoA Template

FINAL LOT DISPOSITION

ACCEPT

Reviewed & Approved By:	<< QA Approver >>
Title:	Scientific QA Representative
Date:	<< Date Approved >>

For sterile products, a Certificate of Irradiation or Processing is also available to assure that the product has received the specified radiation dosage.

For additional information contact us at certificates@ansell.com or visit us at www.ansell.com.

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Minor changes applied to this section for more clarity.

Addition of a contact email for certificates related questions.

Important Note: Only a side-by-side comparison is provided for Sterile and Non-Sterile Cleanroom Gloves as the same principles are applicable to other categories.