The Importance of Quality PPE Ann Van den Borre November 2020 **Ansell** HyFlex GAMMEX AlphaTec MICR@FLEX*

CONTENTS

- 1. Introduction
- 2. Challenges for Selecting Consumables in Clean and Controlled Areas
- 3. Product tests for cleanroom consumables
- 4. Summary of PPE Regulation changes
- 5. Tools and Documentation







A Highly Regulated Industry

Operations in cleanrooms and controlled environments







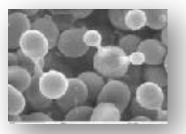


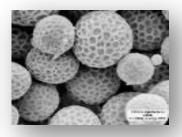
One of the most regulated industrial sector - Overriding industrial and medical requirements

Cleanliness is key - aim to keep operations and end-product free of contamination

- Contamination control
- Cleanrooms
- Sterile production
- RABS









Cleanroom Classifications

ISO (ISO14644)

The logarithm base 10 of the theoretical concentration of particles of 0.1 µm

ISO	Max. particles /m³ air ≥ 0.1 µm	≥ 0.5 µm
	· · · · · · · · · · · · · · · · · · ·	
4	10,000	352
5	100,000	3,520
6	1,000,000	35,200
7	10,000,000	352,000
8	100,000,000	3,520,000

Class

(Old federal standard 209E)

Max. amount of particles of size > 0.5 μm per ft³ of air per minimum 1 minute



Class	Max. particles /ft³ air ≥ 0.5 µm	Generally comparable to
1	1	
10	10	ISO 4
100	100	ISO 5
1000	1000	ISO 6
10 000	10 000	ISO 7
400.000	400.000	100.0

Cleanroom Classifications

GRADE

Annex 1 to EU Guide to Good Manufacturing Practice

Manufacture of Sterile Medicinal Products

	Maximum permitted number of particles per m ³ equal to or greater than						
Grade	at rest (b)		in operation				
	0.5 μm	5.0 μm	0.5 μm	5.0 μm			
Α	3520	20	3520	20			
В	3520	29	352 000	2900			
С	352 000	2900	3 520 000	29 000			
D	3 520 000	29 000	Not defined	Not defined			







What about consumables for controlled and clean environments?

Medical Devices

• Ingitty regulated by MDD regulation, However intended for medical purposes (patient contact)

Personal Protective Equipment

• rocused on protecting the wearer from nazards, highly Regulated in Europe by PPE Regulation

Uncertified products

• Theoretically an option, but no independent control

*for State of California, there is Prop 65 (= self certification) *for food contact, the FDA indirect Food regulations apply - 21 CFR 177 *For PPE specifically, nothing exists except for fire fighter PPE that requires NFPA compliance & certification



Cleanliness – Cleanroom Compatibility

Cleanliness of Application / Cleanroom

- Air cleanliness
 # particles/m³
- Compatibility with certain contaminants

Cleanliness of Product

- Product surface cleanliness IEST-RP-CC005.4 # particles/cm² lonic extractables
- After processing and packing environment
- Frequency of testing of cleanliness parameters

No regulatory requirements for glove cleanliness testing

There is no link



Cleanroom Glove Selection Example

Things to consider....

- Cleanliness based upon provided data by the manufacturer
- Cleanliness based upon outside lab testing
- Sterile or non-sterile
- Single or double gloving
- Glove length 300 mm, 400 mm, 600 mm
- Protection needed chemical, microbiological, viral
- Hand specific or ambidextrous
- Textured or smooth finish
- Material (natural rubber, polychloroprene, nitrile)
- Colour
- Cost













Product Cleanliness Testing

- There is no standard to claim class or ISO for products, any such claims are arbitrary
- Generally accepted by the industry however is data based upon IEST-RP-CC-005
- We can test relevant cleanliness parameters on products;
 - LPC
 - lonic extractables
 - Surface cleanliness
 - Helmke Drum
 - TNVR
 - Absence of silicone oil, amines, DOP



IEST-RP-CC005

Institute of Environmental Sciences and Technology Recommended Practice – Contamination Control – latest version 005.4

Liquid Particle Count

measures readily available surface particles and those released during prescribed, controlled conditions. Glove sample soaked and shaken in water, particles present in extract measured with automated liquid particle counter (particles/cm²)

e.g. LPC (Liquid Particle Count, particles >0.5 µm) ≤ 2500 particles/cm²

Extractable Matter - Ionic Extractables

specific extraction in DI water and measurements of relevant ions (µg/cm²)

```
e.g. Calcium Ca2+ <0.500
Chloride Cl- <0.600
Nitrate NO3- <0.800
Sulphate SO4 2- <0.200
```





IEST-RP-CC005

Total Non-Volatile Residue

Extraction of soluble matter and analysis of the inorganic, organic and total non-volatile residue

Outgassing

measures TWL (Total Weight Loss) of the product after having been placed in a vacuum oven at 65°C during 24 hours, thus capturing the volatile substances. The collected volatile substances and water vapor can be measured as a weight percentage (requiring more sophisticated analytical apparatuses)

Others

Ashing
Hydrogen Sulfide
Microorganisms
Corrosion of surfaces



Sterility Specifics

SAL 10⁻⁶

- Sterming Assurance Level
- Probability of unit for being non-sterile after a validation sterilization cycle
- 1 out of 1.000.000

ISO 11137

- Stermzation of healthcare products by radiation (Garrina irradiation by Gobart-60)
- Validation of the sterilization method

VD MAX 25

- Biopuraeri study to substantiate dose
- CFU/unit is below a provided level by applying dose of radiation (25 kGy)





PPE Directive 89/686/CEE → Change to Regulation 2016/425

Focus of PPER 2016/425

- Make it easier to remove dangerous PPE from market
- Improve traceability
- Reinforced and more efficient market control
- Clearer responsibilities for all actors in supply chain

Additional facts that relevant to LS market

- Products are externally controlled (Notified Body)
 - Category III products require annual retesting or external auditing of quality system
- CE-certificate needs to be renewed regularly
 - → Consistent and controlled quality of the product
- New standard for virus penetration





Risk categories instead of PPE categories

Risk	PPE	Certification	
Minimal	Simple Design Category I	Self-certification	(€
Intermediate Design Category II		EC-Type certification	(€
Mortal / Complex Design Irreversible Category III		EC-Type certification, EC- Quality system	C € 0493





Changes EN374:2003 → EN ISO 374:2016



EN ISO374-2016 part 1 – Extended list test chemicals

Code Letter	Chemical	Cas Number	Class
Α	Methanol	67-56-1	Primary alcohol
В	Acetone	67-64-1	Ketone
С	Acetonitrile	75-05-8	Nitrile Compound
D	Dichloromethane	75-09-2	Chlorinated paraffin
Е	Carbone disulphide	75-15-0	Sulphur containing organic compound
F	Toluene	108-88-3	Aromatic hydrocarbon
G	Diethylamine	109-89-7	Amine
Н	Tetrahydrofurane	109-99-9	Heterocyclic and ether compound
L	Ethyl acetate	141-78-6	Ester
J	N-Heptane	142-82-5	Saturated hydrocarbon
K	Sodium hydroxide 40%	1310-73-2	Inorganic base
L	Sulphuric acid 96%	7664-93-9	Inorganic mineral acid
М	Nitric acid 65%	7697-37-2	Inorganic mineral acid, oxidizing
N	Acetic acid 99%	64-19-7	Organic acid
0	Ammonia 25%	1336-21-6	Organic base
Р	Hydrogene peroxide 30%	7722-84-1	Peroxide
Q	Hydrogene fluoride 40%	7664-39-3	Inorganic mineral acid, contact poison
R	Formaldehyde 37%	50-00-0	Aldehyde





EN ISO374:2016 part 1 – new pictograms



If permeation breakthrough time from the extended chemicals list:

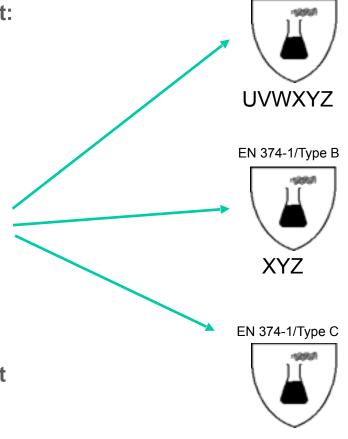


Min 30 min against 6 chemicals

Min 30 min against 3 chemicals

Min 10 min against 1 chemical

from the extended chemicals list









EN 374-1/Type A

New standard for micro-organism risks – EN ISO 374-5:2016

- Protection against bacteria & fungi
 - Testing according to EN374-2:2014 for leakage proofness

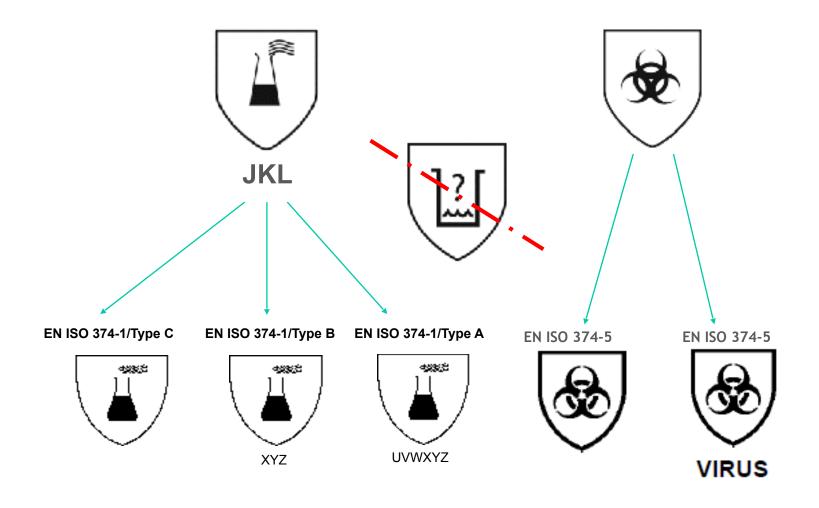


- Protection against bacteria, fungi & virus
 - Testing according to EN374-2:2014 for leakage proofness
 AND
 - Testing according to ISO16604, method B
 - Samples to be taken in palm area & cuff area if length ≥ 40 cm





Summary: Old markings vs new markings







Batch Certificates CoC/CoA/Col

https://www.ansell.com/us/en/life-sciences/certificates

Batch certificates for clean and clean/sterile products

- Overview of specific applicable standards
- LPC and ionic extractables parameters
- Physical product parameters
- Irradiation dose delivered for this batch

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CERTIFICATE OF CONFORMITY & CERTIFICATE OF ANALYSIS

Band	Nititab
Size(s)	8-1.5,99.5,10-10.5
Meterial	Nitile
Slyle	93401
Grom (rescription	Grean Storie Grove
Let Humber	200367
Batch Number	20034012EV
Manufacturing Date	2000-02
Expiration Date	2005-01

DECLARATION OF CONFORMITY

Arest certifier that he above product is nanulactured inaccontance with Arest product specifications and is in contemity with the following numbers or named occurrence.

Standard/Hormative Document	Result
Reach Regulation	Conforms
FbA 2: CFR 177-2000	Conforms
PPER (EU)2016A25	Conforms
Fine from BSE/TSE (SME/V11991)	Gerferns

DECLARATION OF ANALYSIS

Property	Test Mehod	Specification	Result
Glove Length (mm)	ASIM CERCIENZO	min, 300	Conforms
Palm Thickness (mn)	ASIM CERCENCO	min, 0, 1	Conforms
Tensile Strength (MPx)	ASPM DH2	Min. 18	Conforms
Utimate Eurgation (%)	ASPM DH2	min. 500	Conforms
Person from Hules - Final Release	EHRON-IASTM COOTT	G/1, AGE 1.0	Combanna
Liquid Partitia CountS 5-35 p (partition/m/)	WELT-RE-CC008-4	<400	Conforms
Non Volatile Residue NVF (uspirm*)	IEST-RP-CC005.4	48.0	Conforms
Slicons, Anide, DOF - FTIR	IEST-RP-CC005.4	Not detectable	Conforms
Aluminium.A(3+ (µg/m²)	HEST-RIP-CICOUS.4	<0.010	Conforms
Calcium Ca2+ (yg/on*)	IEST-RP-CK008.4	<0.300	Conforms
Criorios C+ (µgorr)	HEST-PER-COOKS.A	~0.200	Conforms
Copper Cu3+ (up/onf)	IEST RECIDERA	-0.0004	Conforms
Inn Felt (splon)	IEST-RP-CC305.4	<0.050	Conforms
Lihium Lin (µg/m²)	IEST-RP-CC305.4	<0.0001	Conforms
Magnesium Mg3+ (µg/om/)	IEST-RP-CC005.4	<0.001	Conforms
NbrateNOI- (µglom ⁵)	IEST-RP-CC005.4	<0.100	Conforms

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Property	Test Nethod	Specification	Result
Potossium K+ (µglom?)	ESTRP-00005.4	<0.020	Conforms
Sodum kla+ (µg/cn²)	ESTRP-00005.4	<0.050	Conforms
Sulphata SO4 2- (ug/cm²)	ESTRP-0008.4	<0.010	Conforms
Dris Disb (pg/cm²)	ESTRP-0000.4	-0.004	Conforms

Bestrinically Signed by: Ann Yam sen Storre

Globa Qualty SrManager - Life-Sciences Solutions Ansell

Date: 35 June 2000

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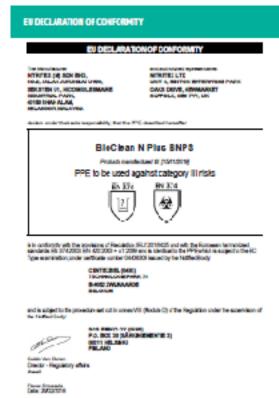






Example of Validation Pack









Available upon request through your sales contact









AnsellGUARDIAN® services

AnsellGUARDIAN®

in-plant assessments to identify application needs and match them with best fitted products

• AnsellGUARDIAN® Partner online chemical risk assessment https://www.ansellguardianpartner.com/chemical/

Permeation Breakthrough Times

The permeation breakthrough times present in this chart were evaluated according to the ASTM F739 standard Colored cells with numbers and symbol (C) correspond to experimentally determined data generated by an accredited laboratory. The rest of cells correspond to estimations.

Mater	ial			Nifrile/Necipre no	Neoprene	Neoprene	Nitrille	Nitrile	Nitrile	Polyisoprene	Natural Rubbor
Thick	ness (mm)			0.18	0.11	0.13	0.17	0.10	0.12	0.21	0.17
Branc	1			MICROFLEX®	DioClean	TouchNTuff®	DioClean	DicClean	Nitrilite	TouchNTuff®	BioClean
Produ	ot Group			93-260.360	BUPS	73-200.600	BNPS	DENS.DJAS.D SAN	03-401	83-300,500	BLAS.BLAS
Турм	GA3	Chemical name	%		Ý	(11)	-	ľ	1		ľ
sqi	64 17 6	Ethanol	70	240 4801	10 301	10/30/	30 60'	10 30"	30 60	<101	10 30
sqi	67 63 0	Isoproponol	70	240 4801	30 601	60 120	30 60,	10 30"	120 240	<10*	p, C
sgi	100-00-3	Toluene 1	100	6' C	f' C	<10'	2" 0	11 C	≺10′	<10°	11 C
sgi	7722-04-1	Hydrogen peroxide	30	400' C	>400' C	>400°	>480' C	36° C	10-301	>400	>400′ c:
Sgl	7847-01-0	Hydrochloric -acid	37	>480° C	448' C	60-1201	SAT C	59° C	60-1201	80-120"	189' C



Topics Which were not Covered Today

There's so much more...

- Chemotherapy drugs, ASTM 6978
- Chemical resistance ASTM F739, EN374
- Specificities on isolator gloves
- Surface cleanliness IEST-STD-CC1246
- PPE Regulation and Standards in detail
- Differences in materials
- Antistatic properties
- We have many assets available on our resource centre on Ansell.com https://www.ansell.com/us/en/life-sciences/business-areas/production-manufacture/resource-download-center





Ansell's organization: 3 Key Platforms

Ansell has 3 platforms to address the needs for the different customers..."

EXAM & SINGLE USE	SURGICAL & SAFETY SOLUTIONS	LIFE SCIENCES		
MICROFLEX* TouchNTuff EDGE* Medical exam gloves Industrial Grade Disposable Gloves	GAMMEX* ENCORE* SANDEL* Surgical MDD gloves	TouchNTuff MICR®FLEX Clean & Sterile Disposable Gloves, Garments, Goggles and other Cleanroom Consumables		









The Ansell Life Sciences Portfolio

FAST FACTS

- Extensive portfolio of protection solutions suitable for laboratory and research, production and manufacturing and controlled and critical environments
- Product categories include gloves, protective clothing, goggles, face masks and RABS & isolator gloves
- Serving customers within healthcare and industrial













