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inform®

Sempermed® Surgical gloves are now even safer

Because the **greatest dangers everyday in hospitals are often invisible,** Sempermed makes its **surgical glove portfolio even safer.** All **Sempermed surgical gloves will run through two independent testing sites as of September 2015,** and are licensed both as medical devices as well as personal protective equipment. In addition, as protection from micro-holes, we are reducing a large portion of our surgical glove portfolio (for products see table 2) to the outstanding **AQL value of 0.65.**

Double Protection

Double certified patient and user protection through a second testing site In addition to medical testing, surgical gloves will also undergo testing by the Test Site for Personal Protective Equipment (PPE) from September 2015. For the improved protection of patients and users.

AQL 0.65

Reduced hole defect rate to AQL 0.65. All synthetic surgical gloves (Sempermed® Syntegra UV, Sempermed® Syntegra IR and Sempermed® Syntegra green), as well as the latex surgical gloves Sempermed® Supreme, Sempermed® Supreme plus, Sempermed® Supreme green and Sempermed® Derma plus are reduced from AQL 1.0 to AQL 0.65.

MD + PPE

Expanded Purpose. In addition, the double designation of the surgical gloves as medical device (MD) and personal protective equipment (PPE) enables an expanded purpose. Even more flexibility with the highest protection.

Sempermed quality gloves with AQL 0.65

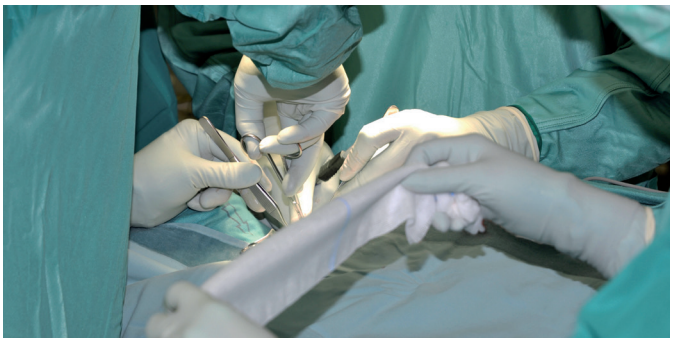
Surgical gloves have to fulfil high requirements in the operating theatre: Tear resistance, impermeability, grip, wearer comfort and viral resistance. Used materials as well as manufacturing- and quality processes contribute to safety and trust.

Because the greatest dangers everyday in hospitals are often invisible, an **as low as possible pinhole rate** of the gloves is an essential factor to secure the safety of the patient and the glove wearer. European standards prescribe that gloves are tested to potential pinhole rates in the course of the quality process. The required quality level is determined by the **AQL for freedom from pinholes (Acceptable Quality Level).**

To offer the best possible protection, Sempermed tests the major part of its surgical gloves range **stricter than required by the European standard** and lowers the AQL for freedom from pinholes from 1.0 to the value of 0.65.
The combination of perfectly set, stable production processes and well-engineered formulation compounds enable us to set **AQL 0.65 as the new internal quality standard for pinhole rates – for even more protection for the surgical staff.**

How is AQL determined?
The determination of the AQL is a statistical method for determining quality. It is described in a precisely defined procedure whereby a defined amount of samples is taken from the total amount of produced goods (batch). This sample is taken and tested according to determined standards and specifications. From the results gained a conclusion on the quality of the total amount of produced goods can be drawn. The higher the qualitative requirements for a product are, the higher are the prescribed guidelines and the lower is the AQL value.

A type of glove for everyday medical activities



Surgical gloves are subject to the strict medical standards of the Medical Devices Directive (MDD). **To increase user flexibility, as of September 2015, all Sempermed® surgical gloves will be designated as personal protective equipment (PPE) in addition to their designation as medical devices (MD).** This expanded purpose enables, in many cases, the same type of glove to be used for various activities in everyday medical activities. The manufacturer can decide whether a glove will be advertised as a medical device or as personal protective equipment. If there were **risks in the interaction between the glove wearer and a patient,** the glove fell under the **EU directive for Medical Devices (MDD 93/42/EEC)** and as a result are considered medical products. If the glove protected against extreme risks, it fell under the EU directive for Personal Safety Equipment. This classification always led to misunderstandings.

The **revised Medical Device Directive 93/42/EEC** now enables manufacturers to **simultaneously classify medical devices also according to the PPE Directive 89/686/EEC as personal protective equipment.** In addition, a manufacturer **must fulfil** the fundamental requirements of **both directives** as well as the **certification procedure at independent test sites.** The advantage for the user is the **expanded purpose** in addition to the double certification. For clear orientation, Sempermed classifies the double designated surgical gloves pursuant to both the Medical Device Directive and the protection category pursuant to the Personal Protective Equipment Directive.

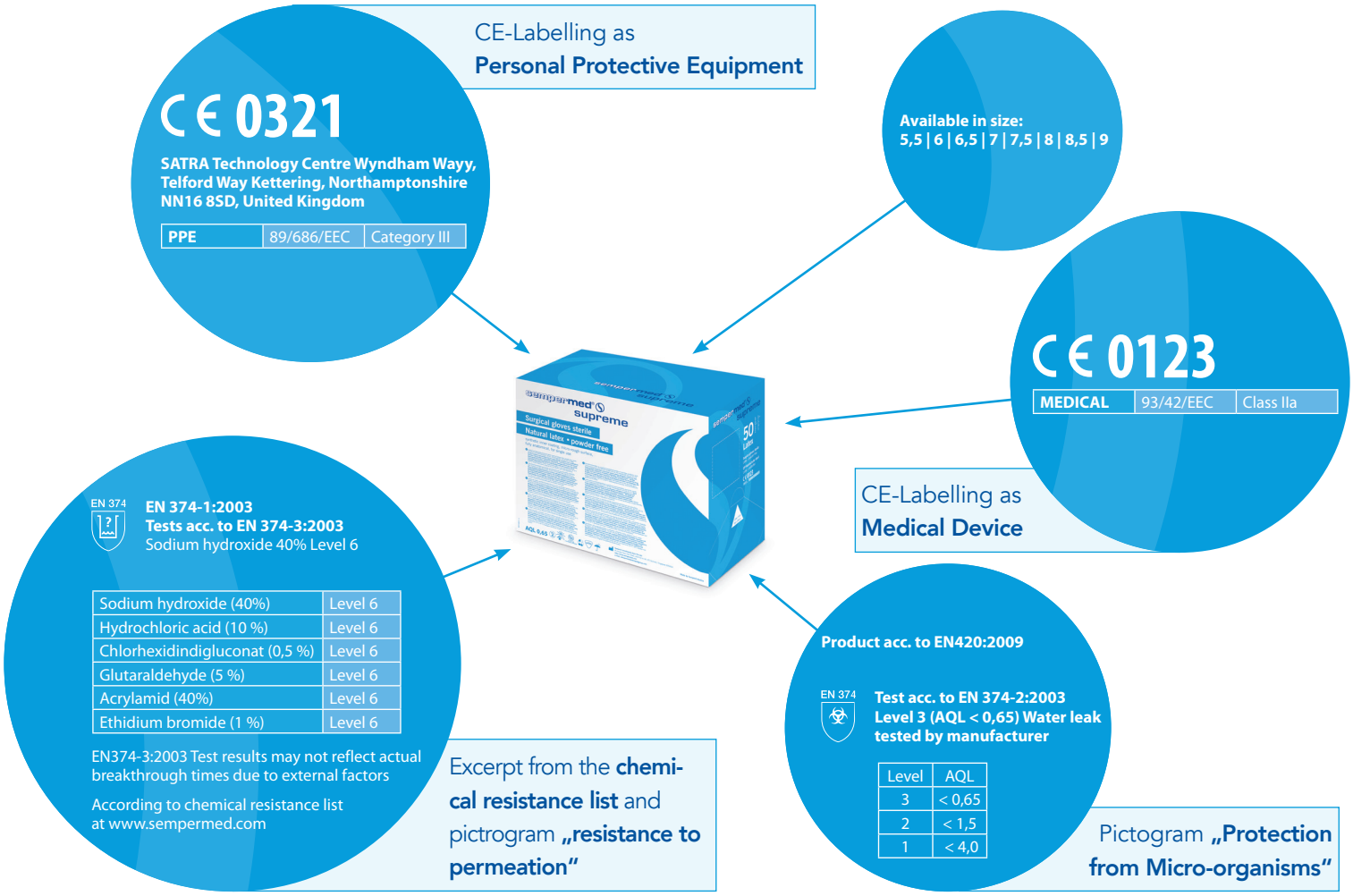
Classification of surgical gloves as personal protective equipment

Directive 89/686/EEC specifies the basic requirements that are demanded of PPE to protect the health and guarantee the safety of the user (e.g., protection level, comfort, and effectiveness of the PPE). **Category III** is relevant to surgical gloves:

Category III: Personal protective equipment complex design for complex risks
Protection from complex risks means protection from irreversible risks, such as permanent damage when handling chemicals. For this purpose, there is an excerpt from the chemical resistance data pursuant to EN 374-3 on the packaging, or the user can request the data from the manufacturer. PPE in Category III must have the certification of an accredited test centre and remains subject to annual controls by the certifier (e.g. SATRA Technology UK). The identification number of the test centre is therefore indicated on the CE label.

CE Label:
CE labelling is required for all PPE. EU declarations of conformity and technical documents are a precondition for this. By adding the CE label, the manufacturer confirms the product's compliance with the EU directive 89/686/EU and the related harmonized standards.

Pictogram Labelling:
The requirements of the PPE directive are implemented through harmonized standards (such as EN 420), which represent the technical standard in the European area and stand for compliance with the EU legislation. The pictograms and labels listed there provide a valuable orientation aid for the user and are tested by the certification centre.



Protective gloves against hazardous chemicals and micro-organisms – EN 374 – Part 2: Determination of resistance to penetration

- The pictogram „Protection from Micro-organisms" denotes any glove which fulfils at least performance level 2 of the **penetration test.**

EN 374

- This symbol, with the additional „level 3" is comparable to the AQL 0.65 for hole rates (resistance to penetration) for medical gloves. Most of the Sempermed® surgical gloves reach this level (see table 2).

Performance Level	AQL-Level
Level 3	< 0.65
Level 2	< 1.5
Level 1	< 4.0

Protection from low chemical hazards:

- The beaker symbol confirms a certain resistance to chemicals **(resistance to permeation).**

EN 374

- To have the pictogram, the glove must achieve at least protection class 2 in the permeation testing of a model test chemical pursuant to EN374-1, appendix A. This represents a breakthrough time of >30 min*.

Measured Breakthrough Time	Protection Class
> 10 Minutes	Level 1
> 30 Minutes	Level 2
> 60 Minutes	Level 3
> 120 Minutes	Level 4
> 240 Minutes	Level 5
> 480 Minutes	Level 6

* EN374-3:2003: Test results may not represent actual breakthrough times due to external factors

Some of the chemicals tested on the product are indicated on the dispenser packs of the Sempermed® surgical gloves with the relevant protection classes. However, a surgical glove is not a full-fledged chemical protection glove. For most of the tested substances, the glove is only recommended as a splash protection and should be changed immediately upon contact. Please note that the properties of a glove are directly dependent on the conditions in which it is used and the chemical purity. When handling hazardous materials, gloves must be always checked for any holes or tears to ensure the relevant protection. There is an excerpt from the Chemical Resistance List in the table below.

CHEMICAL (SYNONYMS)	CAS	SURGICAL GLOVES				
		SEMPERMED® Supreme	SEMPERMED® Syntegra IR	SEMPERMED® Supreme Green	SEMPERMED® Derma PF	SEMPERMED® Syntegra UV
		Latex	Polyisopren (Latex free)	Latex	Latex	Polyisopren (Latex free)
Acetic acid (10 %) (methylcarbon acid)	64-19-7	Level 6	Level 6		Level 4	Level 5
Acetone (2-propanone, methyl ketone)	67-64-1	X	X	X	X	X
Acetonitrile (cyanomethane, ethyl nitrile)	75-05-8	A	A		A	X
Acrylamid (40 %) acrylic acid amide)	79-06-1	Level 6	Level 6		Level 6	Level 6
Ammoniumhydroxid (25%)	1336-21-6	A	Level 1		A	Level 1
Chlorhexidindigluconat (0.5 %)		Level 6	Level 6		Level 6	Level 6
Chlorhexidin (4 %) Level 6* Level 6*		Level 6	Level 6		Level 6	Level 6
Chloroform (trichloromethane, methyl trichloride)	67-66-3	X	X	X	X	X
Cyclohexanol	108-93-0	Level 2	Level 2		A	X
Dichlormethane (methylene chloride, Freon 30)	75-09-2	X	X	X	X	X
Diesel fuel (100 %)		A	A		A	X
Diethylamine (DEA)	109-89-7	X	X	X	X	X
Diethylether (diethyloxid, ethoxyethane, anesthetic ether)	60-29-7	X	X	X	X	X
Dimethylsulfoxide DMSO (deltan, demasorb)	67-68-5	Level 2	Level 3		Level 1	X
Ethanol (20 %) (ethyl alcohol)	64-17-5	A	A	A	A	A
Ethanol (80 %) (ethyl alcohol)	64-17-5	A	A	A	A	A
Ethidium bromide (1%) (homidium bromide)	1239-45-8	Level 6	Level 6		Level 6	Level 6
Ethyl acetate (Aceto acid ether)	141-78-6	A	A	X	X	X
Formaldehyde (37 %) in Methanol (10 %)**	50-00-0	Level 6	Level 6		Level 2*	Level 6
Glutaraldehyde (5 %) (1,3-diformylpropane; Glutaral)	111-30-8	Level 6	Level 6		Level 6	Level 6
Heptan - n	142-82-5	X	X	X	X	X
Hexan - n	110-54-3	X	X	X	X	X

Not recommended
A: only recommended for splash protection - change gloves immediately after contact
Level 1: recommended for short contact (from 10 to 30 min)
Level 2: for applications from 30 to 60 min
Level 3: for applications from 60 to 120 min
Level 4: for applications from 120 to 240 min
Level 5: for applications from 240 to 480 min
Level 6: for applications over 480 min*
Not tested

* Higher measurement values not available

Table 1: Excerpt from the Chemical Resistance List

	Classification of Sempermed® Surgical Gloves	Medical device Class IIa	Personal protective equipment Category III	AQL	
				0.65	1.0 / 1.5
NATURAL LATEX	Sempermed® Supreme	X	X	0.65	
	Sempermed® Supreme plus	X	X	0.65	
	Sempermed® Supreme green	X	X	0.65	
	Sempermed® Derma plus	X	X	0.65	
	Sempermed® Derma PF	X	X		1.0
	Sempermed® Classic	X	X		1.5
SYNTHETIC MATERIAL	Sempermed® Syntegra UV	X	X	0.65	
	Sempermed® Syntegra IR	X	X	0.65	
	Sempermed® Syntegra green	X	X	0.65	

Table 2: Surgical glove product portfolio

[1] Except Sempermed® Classic and Sempermed® Derma PF
[2] For medical gloves resp. surgical gloves the European standard EN 455 part 1 prescribes "general inspection level I" and an AQL level of 1.5
[3] Additional information regarding AQL determination you can find in our publication Sempermed informs No. 2, 5/2015
[4] See also Chemical Resistance List at www.sempermed.com/sempermed-informiert/chemikalienschutz

Impressum
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