



Declaration of Conformity

Product: Surgical Gowns
Product Codes: See attached product list
UMDNS: 11901 (Gown, Operating Room, Disposable)
GMDN: 35091 (Gown, Operating Room, Single Use)
Competent Authority: BE/CA01
EEC Representative: Kimberly-Clark N.V.
Da Vincilaan 1
1935 Zaventem, Belgium

Phone: +32 (0)2 711 2678
Fax: +32 (0)2 711 2695

Product Standards: EN 13795:2011; EN ISO 22610:2006; EN ISO 22612:2005
Classification Rule(s): ONE
Start of CE: 01-Jan-1998

CE-Certification of Medical Device class I or Class I Sterile as per Annex IX of the Council Directive 93/42/EEC.

We hereby declare that the above mentioned devices comply with the British Medical Device Regulations of December 1994 transposing European Medical Devices Directive 93/42/EEC and are in accordance with Annex V and VII of the EEC Directive, supported by the Conformity Assessment Procedure, the EC Certification CE 556098 by BSI Quality Assurance (0086) (for sterile codes only) and adhering to the essential requirements in Accordance with Annex I of the Directive 93/42/EEC.

This declaration is based on the existing Technical Documentation as per Annex VII, paragraph 3. CE marking carried out as per Annex XII of the Directive 93/42/EEC.

This declaration is valid for the products listed on the attached product list in their original, unmodified packaging.

Thomas Kozma, PhD
Kimberly-Clark Healthcare
Director, Regulatory Affairs

Issue Date: 7-July-2014

Kimberly Clark Corporation; 1400 Holcomb Bridge Road, Roswell, GA 30076-2199,
U.S.A.

Phone: +1 770-587-8000 Fax: +1 770 587-7761



Kimberly-Clark Corporation

Annex to the Declaration of Conformity (Product List)

PRODUCT LIST Surgical Gowns

This product list belongs to the Declaration of Conformity identified by Surgical Gowns specifies the CE marked products concerned that Kimberly Clark intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Stock Code	Description	Sterile / Non-Sterile
10550	MicroCool* Breathable Specialty Gown with SECURE-FIT*, X-Large	Sterile - EO
10558	MicroCool* Breathable Specialty Gown with SECURE-FIT*, Large	Sterile - EO
10566	MicroCool* Breathable Specialty Gown with SECURE-FIT*, XX-Large	Sterile - EO
11783	KC100 Surgical Gown, L, with Towels	Sterile – EO
11784	KC100 Surgical Gown, XL, with Towels	Sterile – EO
13234	ULTRA Film-Reinforced Specialty Surgical Gown, Non-Sterile, X-Large	Non-Sterile
13336	KC100 Surgical Gown, X-Large, XX-Long	Sterile – EO
13337	KC100 Surgical Gown, X-Large, XX-Long with Towels	Sterile – EO
13359	MicroCool Breathable High Performance, Small with 2 towels (AUS)	Sterile - EO
13815	KC100 Fabric-Reinforced Surgical Gown, X-Large, XX-Long with Towels	Sterile – EO
13818	KC100 Fabric-Reinforced Surgical Gown, X-Large, XX-Long	Sterile – EO
30734	MicroCool Breathable High Performance Surgical Gown with SECURE-FIT, X-Large, Handi-bin	Sterile – EO
32109	KC100 Surgical Gown, Large, X-Long, with towel and Overlap-HANDI-BIN with removable panel	Non-Sterile
32113	KC100 Surgical Gown, Large, X-Long with towel and Overlap-HANDI-BIN with removable panel	Non-Sterile
33916	KC100 Surgical Gown, Large, with Towel in Overwrap -HAND-BIN with removable panel	Non-Sterile
33917	KC100 Surgical Gown, X Large, with Towel in Overwrap – HANDI-BIN with removable	Non-Sterile
70121	ULTRA Surgical Gown, X-Large	Non-Sterile
70211	ULTRA Fabric-Reinforced Surgical Gown, Large	Non-Sterile
70311	ULTRA Zoned-Impervious Surgical Gown, Large	Non-Sterile

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Stock Code	Description	Sterile / Non-Sterile
70321	ULTRA Zoned-Impervious Surgical Gown, X-Large	Non-Sterile
70391	Surgical Gown, Large, Extra-Long	Non-Sterile
70392	Surgical Gown X-Large, Extra-Long	Non-Sterile
71626	ULTRA Surgical Gown, Large, X-Long	Non-Sterile
71627	Ultra Surgical Gown, X-Large, X-Long	Non-Sterile
72038	MicroCool* Breathable Impervious Gown, Large, X-Long	Non-Sterile
72041	MicroCool* Breathable Impervious Gown, X-Large, X-Long	Non-Sterile
72052	MicroCool* Breathable Specialty Gown, X-Large	Non-Sterile
72311	Ultra zoned impervious gown, Large, non-sterile	Non-Sterile
72438	MicroCool* Breathable Impervious Gown, Large	Non-Sterile
72445	MicroCool* Breathable Impervious Gown, XX-Large	Non-Sterile
72447	MicroCool* Breathable Impervious Gown with SECURE-FIT*, XX-Large	Non-Sterile
72448	MicroCool* Breathable Impervious Gown with SECURE-FIT*, XX-Large	Non-Sterile
72451	MicroCool* Specialty Breathable Impervious Gown, Large	Non-Sterile
72453	MicroCool* Specialty Breathable Impervious Gown X-Large	Non-Sterile
72454	MicroCool* Breathable Impervious Gown with SECURE-FIT*, Large	Non-Sterile
72455	MicroCool* Breathable Impervious Gown with SECURE-FIT*, X-Large	Non-Sterile
72457	MicroCool* Specialty Breathable Impervious Gown, XX-Large	Non-Sterile
72878	Non-Reinforced Surgical Gown with Set-in Sleeves, Large	Non-Sterile
72978	Non-Reinforced Surgical Gown with Set-In-Sleeves, Large, HANDI-BIN	Non-Sterile
72988	Non-Reinforced Surgical Gown w/Set-In-Sleeves, X-Large, in HANDI-BIN	Non-Sterile
73038	MicroCool* Breathable Impervious Gown, Large, X-Long	Non-Sterile
73039	MicroCool* Breathable Impervious Gown, Large	Non-Sterile
73041	MicroCool* Breathable Impervious Gown, X-Large, X-Long	Non-Sterile
73043	MicroCool* Breathable Impervious Gown, X-Large	Non-Sterile

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Stock Code	Description	Sterile / Non-Sterile
73046	GOWN M/COOL KCL SURG N/S XXL	Non-Sterile
73049	MicroCool* Specialty Breathable Impervious Gown, Large	Non-Sterile
73052	MicroCool* Specialty Breathable Impervious Gown, X-Large	Non-Sterile
74115	ULTRA Surgical Gown, Non-sterile, Large, Handibin	Non-Sterile
74116	ULTRA Surgical Gown, Non-sterile, X-Large, Handibin	Non-Sterile
74411	ULRA Film-Reinforced Surgical Gown, Non-Sterile, Large	Non-Sterile
74421	ULTRA Film-Reinforced Surgical Gown, Non-Sterile, X-Large	Non-Sterile
74431	ULTRA Film-Reinforced Surgical Gown, Non-Sterile, XX-Large	Non-Sterile
74911	ULTRA Fabric-Reinforced Surgical Gown, Large	Non-Sterile
74921	ULTRA Fabric-Reinforced Surgical Gown, X-Large	Non-Sterile
74931	ULTRA Fabric-Reinforced Surgical Gown, XX-Large	Non-Sterile
76240	Surgical Gown Pack	Sterile - EO
76521	ULTRA Film-Reinforced Specialty Surgical Gown, Non-Sterile, X-Large	Non-Sterile
76531	ULTRA Film-Reinforced Specialty Surgical Gown, Non-Sterile, XX-Large	Non-Sterile
77328	ULTRA Fabric-Reinforced Surgical Gown, Large, X-Long	Non-Sterile
77329	ULTRA Fabric-Reinforced Surgical Gown, X-Large, X-Long	Non-Sterile
77336	ULTRA Fabric-Reinforced Surgical Gown, with Neck Protection and Thumbloops, X-Large, X-Long	Non-Sterile
77456	Gown Pack I	Non-Sterile
77465	Gown Pack III	Non-Sterile
78911	Fabric-Reinforced Surgical Gown, Large	Non-Sterile
78913	Fabric-Reinforced Surgical Gown, Large, X-Long	Non-Sterile
78921	Fabric-Reinforced Surgical Gown, X-Large	Non-Sterile
78923	Fabric-Reinforced Surgical Gown, X-Large, X-Long	Non-Sterile
78927	E4 GOWN Fabric-Reinforced N/S HANDI XL	Non-Sterile
78940	Asia Pacific Medium (Ster)	Sterile - EO

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Stock Code	Description	Sterile / Non-Sterile
78945	Asia Pacific Large (Ster)	Sterile - EO
78950	Asia Pacific X-Large (Ster)	Sterile - EO
78955	Asia Pacific XX-Large (Ster)	Sterile - EO
79284	KC100 Surgical Gown, L	Non-Sterile
79285	KC100 Surgical Gown, XL	Non-Sterile
79294	KC100 Surgical Gown, Large, Extra-Long	Non-Sterile
79295	KC100 Surgical Gown, X-Large, X-Long	Non-Sterile
79419	Non-Reinforced Surgical Gown with Set-In Sleeves, Large, with Towel in Overwrap - HANDI-BIN	Non-Sterile
79434	Non-Reinforced Surgical Gown with Set-In Sleeves with Towel in Overwrap, X-Large HANDI-BIN	Non-Sterile
79729	MicroCool* Breathable Impervious Gown, Large - HANDI-BIN	Non-Sterile
79739	MicroCool* Breathable Impervious Gown, X-Large - HANDI-BIN	Non-Sterile
79830	EVOLUTION SURGICAL GOWN M (Non-Ster)	Non-Sterile
79831	EVOLUTION SURGICAL GOWN XXL (Non-Ster)	Non-Sterile
79870	Non-Reinforced Surgical Gown, Large	Non-Sterile
79873	SURGICAL GOWN, LARGE, X-LONG	Non-Sterile
79970	Non-Reinforced Surgical Gown, Large	Non-Sterile
79973	Surgical Gown, Large, X-Long	Non-Sterile
79980	Non-Reinforced Surgical Gown, X-Large	Non-Sterile
79983	Surgical Gown, X-Large, X-Long	Non-Sterile
89791	Sterile Sleeve, 6 in. x 23.5 in./15 cm x 59 cm	Sterile - EO
90002	Surgical Gown, Small, with Towel	Sterile - EO
90003	Surgical Gown, Small/Medium with 2 Towels	Sterile - EO
90012	Surgical Gown, Large, with Towel	Sterile - EO
90013	Surgical Gown, Large, X-Long, with Towel	Sterile - EO
90016	Surgical Gown, Large, with Towels	Sterile - EO

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90018	Surgical Gown, Large	Sterile - EO
90019	Surgical Gown, Large, X-Long, with Towels	Sterile - EO
90042	Surgical Gown, X-Large, with Towel	Sterile - EO
90043	Surgical Gown, X-Large, X-Long, with Towel	Sterile - EO
90046	Surgical Gown, X-Large, with Towels	Sterile - EO
90048	Surgical Gown, X-Large with Towels	Sterile - EO
90050	Surgical Gown, XX-Large with 2 towels	Sterile - EO
90112	Fabric-Reinforced Surgical Gown, Large, with Towel	Sterile - EO
90113	Fabric-Reinforced Surgical Gown, Large, X-Long, with Towel	Sterile - EO
90138	Surgical Gowns with Huck Towels (Twin Pack -Size L & XL), Sterile	Sterile - EO
90142	Fabric-Reinforced Surgical Gown, X-Large, with Towel	Sterile - EO
90143	Fabric-Reinforced Surgical Gown, X-Large, X-Long, with Towel	Sterile - EO
90363	Ultra Fabric-Reinforced Surgical Gown, Large, X-Long, with Neck Protection and Thumb Loops, with Towel	Sterile - EO
90373	ULTRA Fabric-Reinforced Surgical Gown, X-Large, X-Long, with Neck Protection and Thumb Loops, with Towel	Non-Sterile
92037	MicroCool* Breathable Impervious Gown, Large, with Towels	Sterile - EO
92038	MicroCool* Breathable Impervious Gown, X-Long, Large, with Towels	Sterile - EO
92039	MicroCool Breathable Impervious Gown, Large, with Towel	Sterile - EO
92040	MicroCool* Breathable Impervious Gown, X-Large, with Towels	Sterile - EO
92042	MicroCool* Breathable Impervious Gown, X-Large, X-Long, with Towels	Sterile - EO
92049	MicroCool* Breathable Specialty Gown, Large, with Towel	Sterile - EO
92043	MicroCool* Breathable Impervious Gown, X-Large, with Towel	Sterile - EO
92320	KC400 MicroCool* Breathable Impervious Gown, with SECURE-FIT*, with Towel, Large	Sterile - EO
92321	KC400 MicroCool* Breathable Impervious Gown, with SECURE-FIT*, with Towel, X-Large	Sterile - EO
92323	KC400 MicroCool* Breathable Impervious Gown, with SECURE-FIT*, with Towel, XX-Large	Sterile - EO
92330	KC400 MicroCool* Breathable Specialty Gown, with SECURE-FIT*, with Towel, Large	Sterile - EO

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92331	KC400 MicroCool* Breathable Specialty Gown, with SECURE-FIT*, with Towel, X-Large	Sterile - EO
92333	KC400 MicroCool* Breathable Specialty Gown, with SECURE-FIT*, with Towel, XX-Large	Sterile - EO
92336	KC400 MicroCool* Breathable Impervious Gown with Towel, Small	Sterile - EO
92338	MicroCOOL* Breathable Impervious Gown, With SecureFit, Sterile, Small	Sterile - EO
92339	MicroCool* Breathable Impervious Gown with SECURE-FIT*, Large, with Towel	Sterile - EO
92340	KC400 MicroCool* Breathable Impervious Gown with Towel, Large	Sterile - EO
92342	KC400 MicroCool* Breathable Impervious Gown with Towel, X-Large	Sterile - EO
92344	KC400 MicroCool* Breathable Impervious Gown with Towel, XX-Large	Sterile - EO
92347	KC400 MicroCool* Breathable Surgical Gown with SECURE-FIT*, XXX-Large	Sterile - EO
92351	KC400 MicroCool* Breathable Specialty Gown with Towel, Large	Sterile - EO
92353	KC400 MicroCool* Breathable Specialty Gown with Towel, X-Large	Sterile - EO
92354	KC400 MicroCool* Breathable Impervious Gown with SECURE-FIT*, Large, with Towel	Sterile - EO
92355	KC400 MicroCool* Breathable Impervious Gown with SECURE-FIT*, X-Large, with Towel	Sterile - EO
92357	KC400 MicroCool* Breathable Specialty Gown with Towel, XX-Large	Sterile - EO
92358	MicroCOOL* Breathable Impervious Gown, With SecureFit, Sterile, XX-Large	Sterile - EO
95101	ULTRA Surgical Gown, Small	Sterile - EO
95111	ULTRA Surgical Gown, Large, with Towel	Sterile - EO
95113	ULTRA Surgical Gown, Large, with Towels	Sterile - EO
95114	ULTRA Surgical Gown, Large, X-Long, with Towels	Sterile - EO
95121	ULTRA Surgical Gown, X-Large, with Towel	Sterile - EO
95123	ULTRA Surgical Gown, X-Large, with Towels	Sterile - EO
95124	ULTRA Surgical Gown, X-Large, X-Long, with Towels	Sterile - EO
95131	ULTRA Surgical, XX-Large, with Towel	Sterile - EO
95201	GOWN ULTRA REINFORCED SML X1	Sterile - EO
95211	ULTRA Fabric-Reinforced Surgical Gown, Large, with Towel	Sterile - EO

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95214	ULTRA Fabric-Reinforced Surgical Gown, Large, X-Long, with Towel	Sterile - EO
95221	ULTRA Fabric-Reinforced Surgical Gown, X-Large, with Towel	Sterile - EO
95224	ULTRA Fabric-Reinforced Surgical Gown, X-Large, X-Long, with Towel	Sterile - EO
95311	ULTRA Zoned-Impervious Surgical Gown, Large, with Towel	Sterile - EO
95321	ULTRA Zoned-Impervious Surgical Gown, X-Large, with Towel	Sterile - EO
95331	ULTRA Zoned-Impervious Surgical Gown, XX-Large, with Towel	Sterile - EO
95411	ULTRA Film-Reinforced Surgical Gown, Large	Sterile - EO
95421	ULTRA Film-Reinforced Surgical Gown, X-Large	Sterile - EO
95431	ULTRA Film-Reinforced Surgical Gown, XX-Large	Sterile - EO
95511	ULTRA Film-Reinforced Specialty Surgical Gown, Large	Sterile - EO
95521	ULTRA Film-Reinforced Specialty Surgical Gown, X-Large	Sterile - EO
99294	KC100 Surgical Gown, Large, Extra-Long w/Towels	Sterile - EO
99295	KC100 Surgical Gown, X-Large, X-Long w/Towels	Sterile - EO
95311	ULTRA Zoned-Impervious Surgical Gown, Large, with Towel	Sterile - EO
95321	ULTRA Zoned-Impervious Surgical Gown, X-Large, with Towel	Sterile - EO
95331	ULTRA Zoned-Impervious Surgical Gown, XX-Large, with Towel	Sterile - EO
95411	ULTRA Film-Reinforced Surgical Gown, Large	Sterile - EO
95421	ULTRA Film-Reinforced Surgical Gown, X-Large	Sterile - EO
95431	ULTRA Film-Reinforced Surgical Gown, XX-Large	Sterile - EO
95511	ULTRA Film-Reinforced Specialty Surgical Gown, Large	Sterile - EO
95521	ULTRA Film-Reinforced Specialty Surgical Gown, X-Large	Sterile - EO
41928	Aero Blue Performance Surgical Gown, Large	Sterile - EO
41929	Aero Blue Performance Surgical Gown, X-Large	Sterile - EO
41930	Aero Blue Performance Surgical Gown, X-Long, Large	Sterile - EO
41933	Aero Blue Performance Surgical Gown, X-Long, Large	Non- Sterile


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41931	Aero Blue Performance Surgical Gown, X-Long, X Large	Sterile – EO
41934	Aero Blue Performance Surgical Gown, X-Long, X-Large	Non-Sterile

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