

exact

MEDICAL

manufacturing with integrity.



Surgical Gowns Catalog 2023



Exact Medical offers custom capabilities in the design, development and manufacturing of medical devices for distribution worldwide.

As a multicultural company we do more than make surgical gowns, drapes. We offer our partners a peace of mind that we will deliver exactly what they need.

As the owner of the facility in China, we have the unique ability to control your manufacturing process and ensure the utmost in quality.

With Exact Medical, you'll have confidence in our people, our product, and our ability to provide you what you need, when you need it.

Exact Medical helps you realize the cost efficiencies of manufacturing in China, while adhering to rigorous international quality standards.

While China is a world away, you can be confident that when you put your trust in Exact Medical, you'll experience a world of difference

Exact Medical's mission is to offer:

- * Products with the highest concern for consistency in quality and delivery
- * Attentive customer service for a convenient experience
- * Product diversity and successful end result
- * An enhanced environment and opportunities for our employees

What we believe

Design

Whether you have your own product or need help from our experienced staff to develop a product, will customize our production to deliver exactly what you need.

Quality

Using a systematic approach to quality by monitoring every step of the way. This includes material sourcing, validation, production, packaging and delivery to achieve our customer's expectations.

Delivery

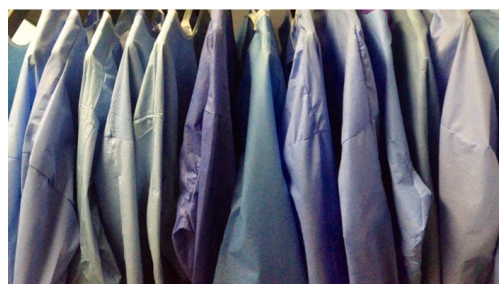
To overcome logistical challenges by providing each customer of ours an effective and efficient delivery plan and attentive customer service.

	Table of content Surgical Gowns	
Chapter	Description	
1.	Surgical Gowns, Introduction	Page 4
2.	EN 13795 Explained	Page 5
3.	Gowns Standard ANSI / AAMI Explained	Page 6
4.	Sterile Surgical Gowns US Market Only	
4.1	Sterile Surgical Gowns Standard AAMI III	Page 7
4.2.	Sterile Surgical Gowns, Poly Reinforced AAMI III	Page 8
4.3.	Sterile Surgical Gowns, Standard Reinforced AAMI IV	Page 9
5.	Sterile Surgical Gowns EU Market Only	
5.1.	Sterile Surgical Gowns, SMS	Page 10
5.2.	Sterile Surgical Gowns, SMS, Poly Reinforced	Page 11
5.3.	Sterile Surgical Gowns, Phoenix	Page 12
5.4.	Sterile Surgical Gowns, Phoenix, Poly Reinforced	Page 13
5.5.	Sterile Surgical Gowns, Spunlace	Page 14
5.6.	Sterile Surgical Gowns, Spunlace, Poly Reinforced	Page 15
6.	NON - Sterile Surgical Gowns	Page 16
7.	Contact information	Page 17

Surgical Gowns

1. Surgical Gowns, Introduction

Exact Medical offers a variety of surgical gowns to meet the needs in the operating room. All Exact Medical's gowns are held to meet EN 13795 as well as AAMI standards. Each gown offered may have a variation of either Spunlace, SMMS or Phoenix, a softer SMS. All of our offered materials and gowns are designed for comfort and flexibility for the end user. Each material and design will not compromise the protection that standards request and the end user's needs.



EN 13795

European Standard EN 13795 aims to establish requirements for surgical drapes, gowns and clean air suits used as medical devices for patients, clinical staff and equipment.

AAMI

The Association for the Advancement of Medical Instrumentation (AAMI) standard, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for use in Health Care Facilities (AAMI/ANSI PB70), provides an objective standard to select the proper level of protection needed for specific procedures.



THE SCOPE OF THE STANDARDS

This Standards specify information to be supplied to users and third party verifiers in addition to the usual labelling of Medical Devices concerning manufacturing and processing requirements. It gives general guidance on the characteristics of singleuse and re-usable surgical gowns, surgical drapes and clean air suits used as medical devices for patients, clinical staff and equipment. It is intended to prevent the transmission of infectious agents between patients and clinical staff during surgical and other invasive procedures.

Surgical Gowns

2. Surgical Gowns, EN 13795 Explained

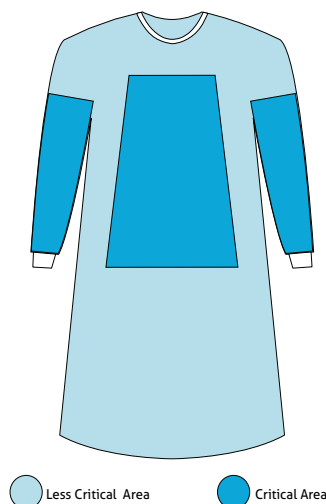
Performance Requirements for Surgical Gowns					
Characteristic	Unit	Standard performance		High Performance	
		Critical area	Less critical area	Critical area	Less critical area
Resistance to microbial penetration - dry	Log ₁₀ (CFU)	N/A	≤ 2 ^{a,c}	N/A	≤ 2 ^{a,c}
Resistance to microbial penetration - wet	BI	≥ 2,8 ^b	N/A	2,8 ^{b,d}	N/A
Cleanliness - microbial	Log ₁₀ (CFU dm ²)	≤ 2 ^c	≤ 2 ^c	≤ 2 ^c	≤ 2 ^c
Cleanliness - particulate matter	IPM	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5
Linting	Log ₁₀	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0
Resistance to liquid penetration	cmH ₂ O	≥ 20	≥ 10	≥ 100	≥ 10
Bursting strength - dry	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength - wet	kPa	≥ 40	N/A	≥ 40	N/A
Tensile strenght - dry	N	≥ 20	≥ 20	≥ 20	≥ 20
Tensile strenght - wet	N	≥ 20	N/A	≥ 20	N/A

a. Test conditions: challenge concentration 108 CFU/g talc. and 30 minutes vibration time.

b. The Least Significant Difference (LSD) for BI when estimated using EN ISO 22610, was found to be 0,98 at the 95% confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. This means materials varying by up to 0,98 BI are probably not different; materials varying by more than 0,98 BI probably are different. (The 95% confidence level means that an observer would be correct 19 times out of 20 to accept these alternatives).

c. For the purpose of this standaard, log₁₀ CFU ≤ 2 means maximum 300 CFU.

d. BI = 6,0 for the purpose of this standaard means: no penetration. BI = 6,0 is the maximum achievable value.



Surgical Gowns

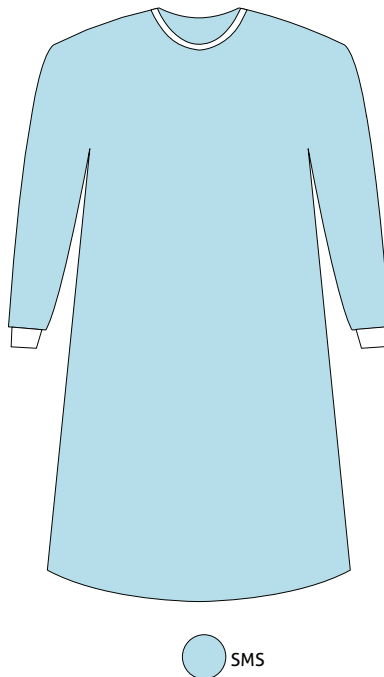
3. Surgical Gowns, Gowns Standard ANSI / AAMI Explained

ANSI/AAMI PB 70:12 Classification of Barrier Performance of Surgical Gowns, Other Protective Apparel, Surgical Drapes and Drape Accessories			
ANSI/AAMI PB 70 Barrier Performance	Test Method	Test Definition	Requirement
Level 1	WaterResistance: Impact Penetration AATCC 42	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact	Water Impact \leq 4.5g
Level 2	WaterResistance: Impact Penetration AATCC 42	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact	Spray Impact \leq 1.0g Hydrostatic Pressure \geq 20cm
	Water Resistance: Hydrostatic Pressure AATCC 127	AATCC 127 Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.	
Level 3	WaterResistance: Impact Penetration AATCC 42	AATCC 42 Measures the resistance of fabrics to the liquid penetration of water by impact	Spray Impact \leq 1.0g Hydrostatic Pressure \geq 50cm
	Water Resistance: Hydrostatic Pressure AATCC 127	AATCC 127 Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.	
Level 4	Synthetic Blood Penetration: ASTM F1670	ASTM F1670 Measures the resistance of fabrics to bloodborne pathogens using viral penetration at 2 psi (pressure per square inch) and ambient pressure.	No Penetration at 2 psi
	Viral Penetration: ASTM F1671	ASTM F1671 Measures the resistance of fabrics to bloodborne pathogens using viral penetration at 2 psi (pressure per square inch) and ambient pressure.	

*** The maximum number of defects per hundred units that, for purpose of inspection, can be considered satisfactory as a process average.

Surgical Gowns US Market Only

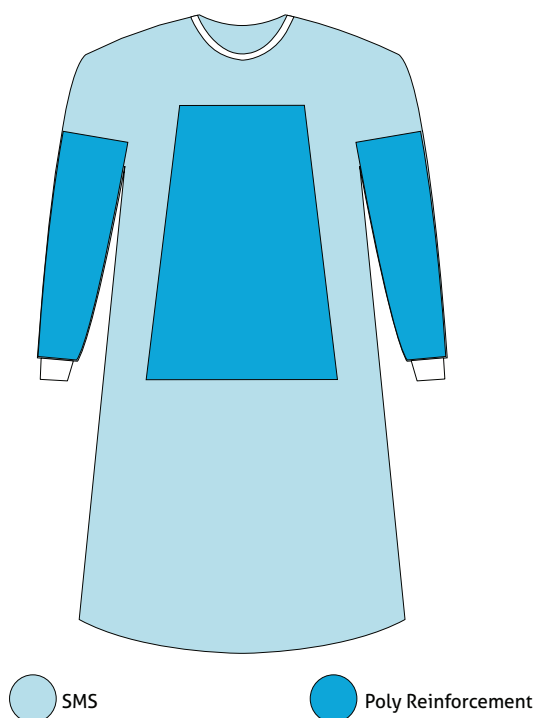
4.1. Sterile Surgical Gowns Standard AAMI III



Code	Description	Size
E105150	Gown Standard AAMI III, Set-In, with Towel	Large
E105160	Gown Standard AAMI III, Set-In, with Towel	Extra Large
E105170	Gown Standard AAMI III, Set-In, with Towel	Extra Extra Large

Surgical Gowns US Market Only

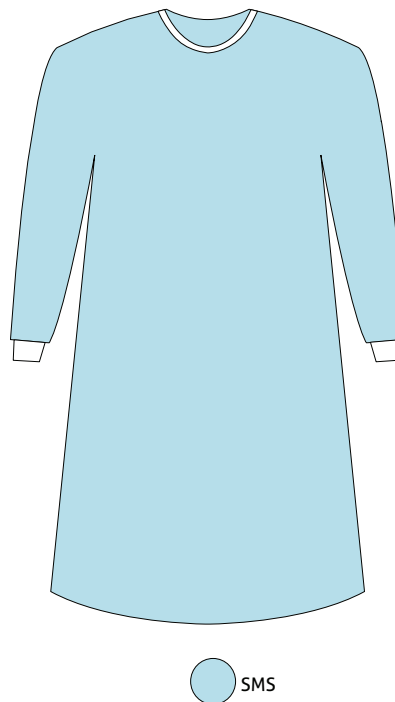
4.2. Sterile Surgical Gowns, Poly Reinforced AAMI III



Code	Description	Size
E100350	Gown Standard Poly Reinforced AAMI III, Set-In, with Towel	Large
E100360	Gown Standard Poly Reinforced AAMI III, Set-In, with Towel	Extra Large
E100370	Gown Standard Poly Reinforced AAMI III, Set-In, with Towel	Extra Extra Large

Surgical Gowns US Market Only

4.3. Sterile Surgical Gowns, Standard Reinforced AAMI IV

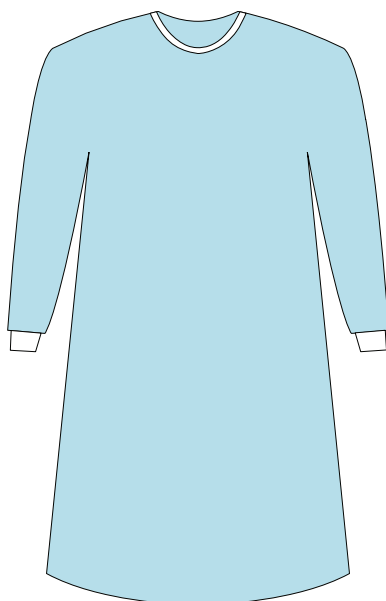


Code	Description	Size
E104450	Gown Standard, Reinforced AAMI IV, Set-In, with Towel	Large
E104460	Gown Standard, Reinforced AAMI IV, Set-In, with Towel	Extra Large
E104470	Gown Standard, Reinforced AAMI IV, Set-In, with Towel	Extra Extra Large

Surgical Gowns EU Market Only

5.1. Sterile Surgical Gowns, SMS

Spunbound-Meltblown-Spunbound (SMS) a composite fabric designed for the growing needs of the medical industry provides increased protection that will not compromise comfort

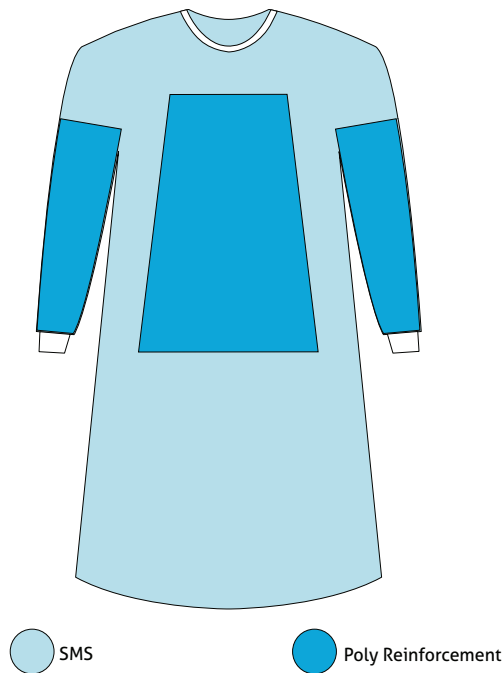


Code	Description	Size
EU000150	Gown Standard, Set-In, with 2 Towels	Large
EU000160	Gown Standard, Set-In, with 2 Towels	Extra Large
EU000170	Gown Standard, Set-In, with 2 Towels	Extra Extra Large
EU000152	Gown Standard, Set-In, with 2 Towels	Large, Extra Long
EU000162	Gown Standard, Set-In, with 2 Towels	Extra Large, Extra Long
EU000172	Gown Standard, Set-In, with 2 Towels,	Extra Extra Large, Extra Long

Surgical Gowns EU Market Only

5.2. Sterile Surgical Gowns, SMS, Poly Reinforced

Spunbound-Meltblown-Spunbound (SMS) a composite fabric designed for the growing needs of the medical industry provides increased protection that will not compromise comfort

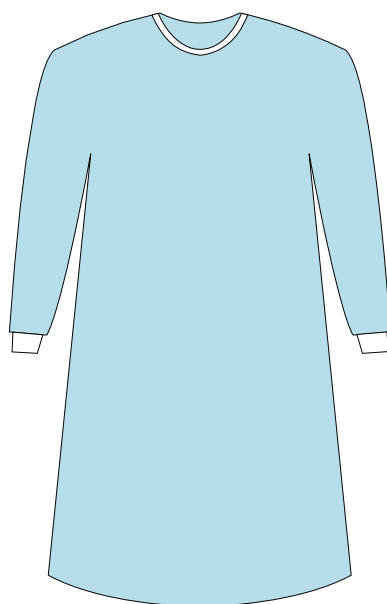


Code	Description	Size
EU000350	Gown Standard, Poly Reinforced, Set-In, with 2 Towels	Large
EU000360	Gown Standard, Poly Reinforced, Set-In, with 2 Towels	Extra Large
EU000370	Gown Standard, Poly Reinforced, Set-In, with 2 Towels	Extra Extra Large
EU000352	Gown Standard, Poly Reinforced, Set-In, with 2 Towels	Large, Extra Long
EU000362	Gown Standard, Poly Reinforced, Set-In, with 2 Towels	Extra Large, Extra Long
EU000372	Gown Standard, Poly Reinforced, Set-In, with 2 Towels	Extra Extra Large, Extra Long

Surgical Gowns EU Market Only

5.3. Sterile Surgical Gowns, Phoenix

Exact's Phoenix, in-house developed SMMS alternative, enhance the natural comfort and drapability of standard SMMS. This material offers the best balance of safety and comfort allowing peace of mind performance



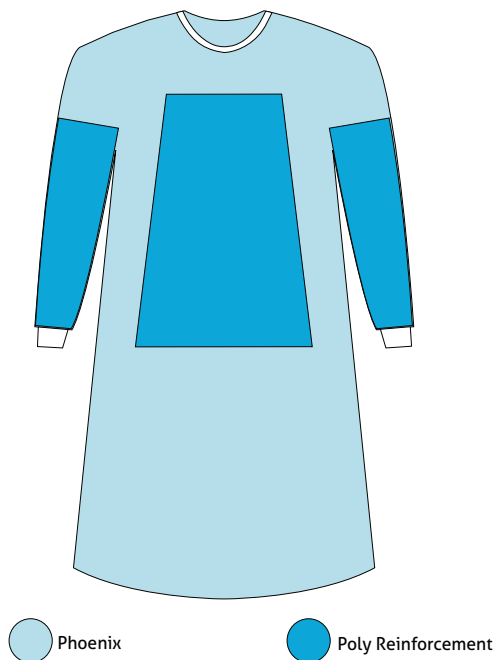
 Phoenix

Code	Description	Size
EU002150	Gown Phoenix Set-In, with 2 Towels	Large
EU002160	Gown Phoenix Set-In, with 2 Towels	Extra Large
EU002170	Gown Phoenix Set-In, with 2 Towels	Extra Extra Large
EU002152	Gown Phoenix Set-In, with 2 Towels	Large, Extra Long
EU002162	Gown Phoenix Set-In, with 2 Towels	Extra Large, Extra Long
EU002172	Gown Phoenix Set-In, with 2 Towels	Extra Extra Large, Extra Long

Surgical Gowns EU Market Only

5.4. Sterile Surgical Gowns, Phoenix Poly Reinforced

Exact's Phoenix, in-house developed SMMS alternative, enhance the natural comfort and drapability of standard SMMS. This material offers the best balance of safety and comfort allowing peace of mind performance

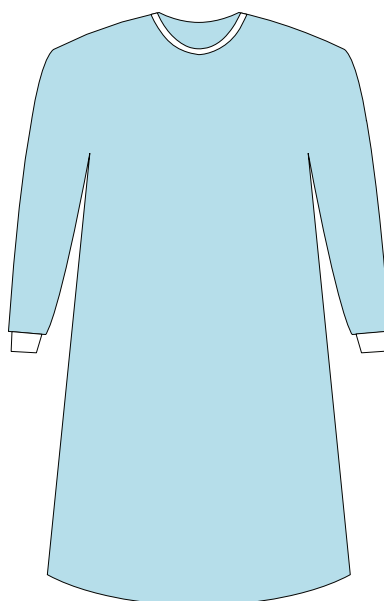


Code	Description	Size
EU002350	Gown Phoenix, Poly Reinforced, Set-In, with 2 Towels	Large
EU002360	Gown Phoenix, Poly Reinforced, Set-In, with 2 Towels	Extra Large
EU002370	Gown Phoenix, Poly Reinforced, Set-In, with 2 Towels	Extra Extra Large
EU002352	Gown Phoenix, Poly Reinforced, Set-In, with 2 Towels	Large, Extra Long
EU002362	Gown Phoenix, Poly Reinforced, Set-In, with 2 Towels	Extra Large, Extra Long
EU002372	Gown Phoenix, Poly Reinforced, Set-In, with 2 Towels	Extra Extra Large, Extra Long

Surgical Gowns EU Market Only

5.5. Sterile Surgical Gowns, Spunlace

Spunlace, manufactured using a wetlaid lattice entanglement of fibers offers leading drapability and structural integrity to protect and comfort both patient and doctor.

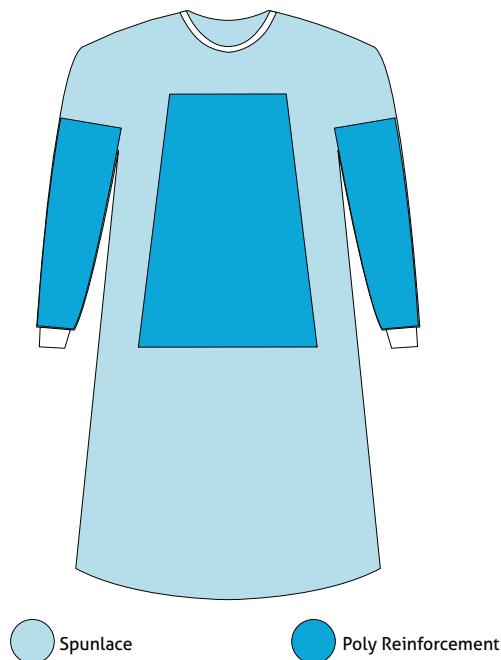


Code	Description	Size
EU003150	Gown Spunlace, Set-In, with 2 Towels	Large
EU003160	Gown Spunlace, Set-In, with 2 Towels	Extra Large
EU003170	Gown Spunlace, Set-In, with 2 Towels	Extra Extra Large
EU003152	Gown Spunlace, Set-In, with 2 Towels	Large, Extra Long
EU003162	Gown Spunlace, Set-In, with 2 Towels	Extra Large, Extra Long
EU003172	Gown Spunlace, Set-In, with 2 Towels	Extra Extra Large, Extra Long

Surgical Gowns EU Market Only

5.6. Sterile Surgical Gowns, Spunlace, Poly Reinforced

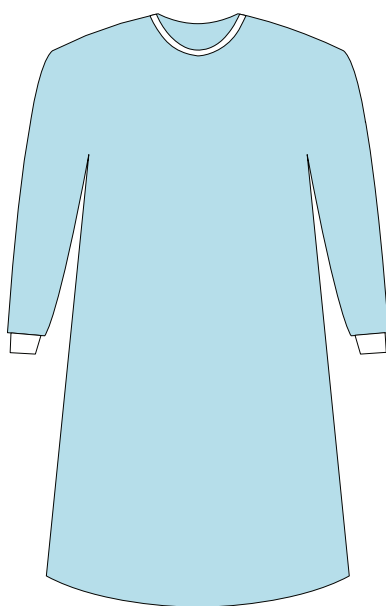
Spunlace, manufactured using a wetlaid lattice entanglement of fibers offers leading drapability and structural integrity to protect and comfort both patient and doctor.



Code	Description	Size
EU003350	Gown Spunlace, Poly Reinforced, Set-In, with 2 Towels	Large
EU003360	Gown Spunlace, Poly Reinforced, Set-In, with 2 Towels	Extra Large
EU003370	Gown Spunlace, Poly Reinforced, Set-In, with 2 Towels	Extra Extra Large
EU003352	Gown Spunlace, Poly Reinforced, Set-In, with 2 Towels	Large, Extra Long
EU003362	Gown Spunlace, Poly Reinforced, Set-In, with 2 Towels	Extra Large, Extra Long
EU003372	Gown Spunlace, Poly Reinforced, Set-In, with 2 Towels	Extra Extra Large, Extra Long

Surgical Gowns NON Sterile US Market and EU Market

6. NON - Sterile Surgical Gowns



All our surgical gowns mentioned in this catalog are available in different quantities, packaging and are also available in non-sterile versions. Please contact your local customer service for further information, packaging and pricing.

7. Contact Information



***"A global source for quality Surgical
Drapes, Gowns and Equipment Covers"***

Europe

Exact Medical B.V.
Kerkstraat 35
5253 AN Nieuwkuijk
The Netherlands

Phone: +31-73 760 0675

Fax: +31-73 760 0676

Email: cs-eu@exactmm.com

Website: www.exactmm.com

United States

Exact Medical Manufacturing Inc.
4917 William Street,
Lancaster, NY 14086
United States of America

Phone: +1 716 681 0076

Fax: +1 716 681 4110

Email: info@exactmm.com

Website: www.exactmm.com