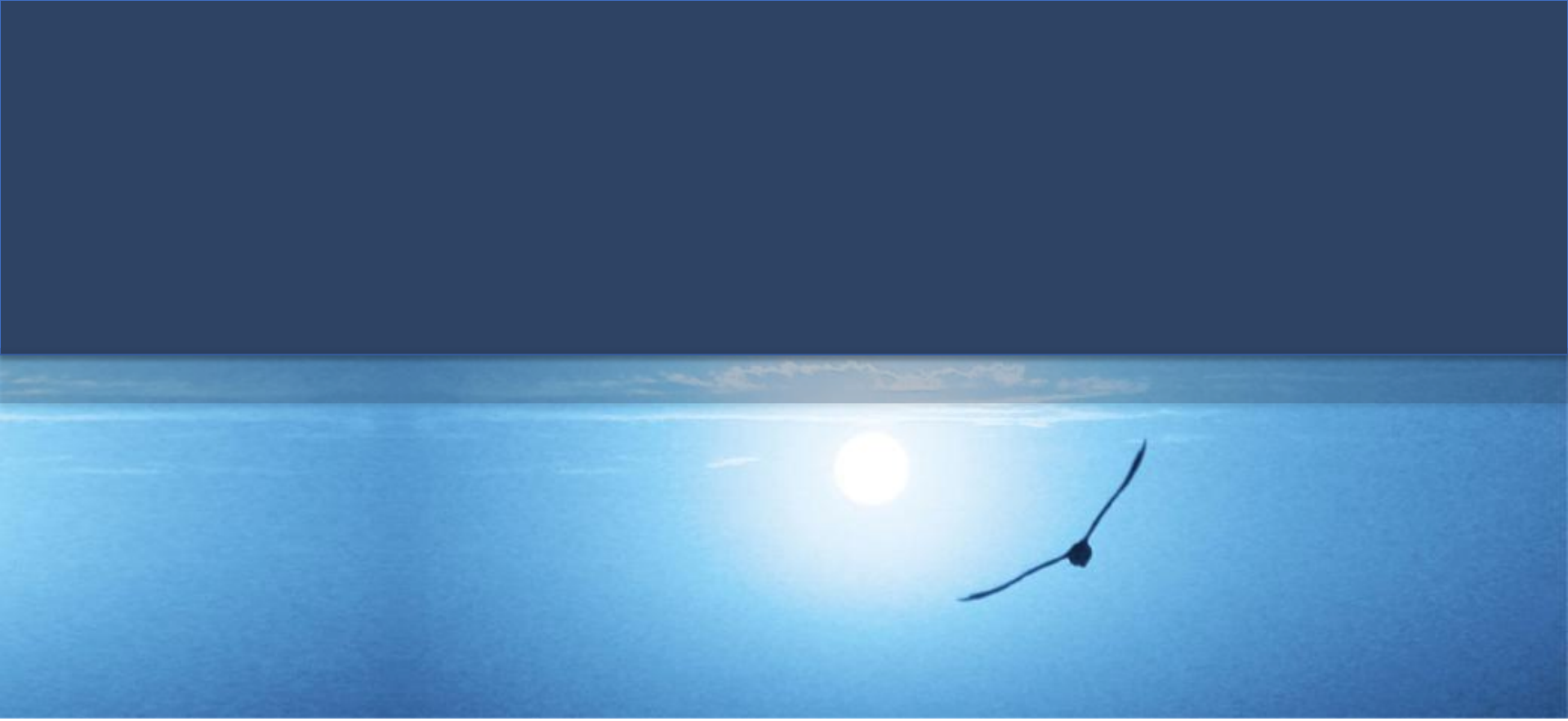


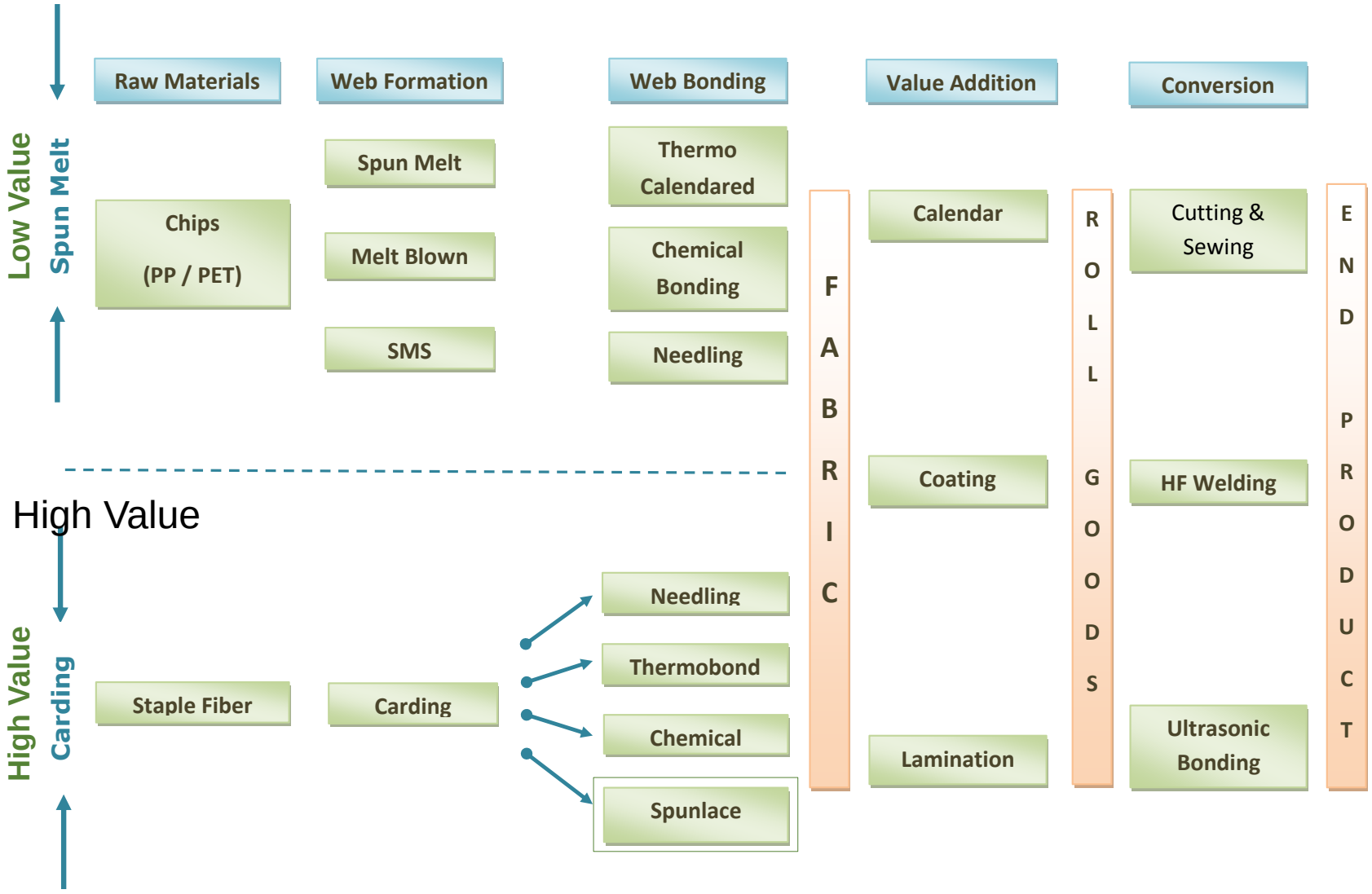
Nonwoven - Hygiene & Medical Applications

Introduction to Nonwovens

What are Nonwovens?

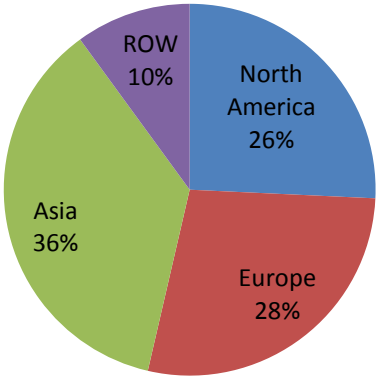
"Nonwovens are a unique class of textile material formed from fibres that are bonded together through various means to form a coherent structure."

Nonwoven Manufacturing Processes

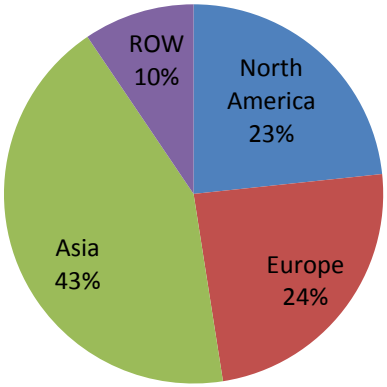


Global Consumption of Nonwovens

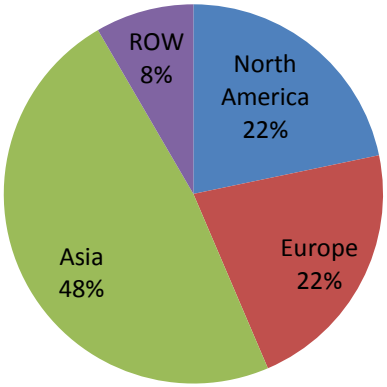
2010

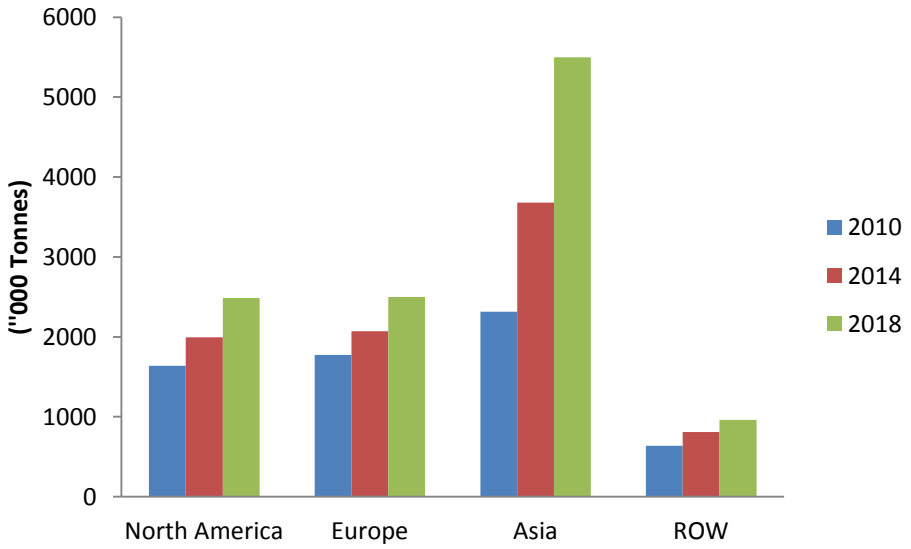


2014



2018





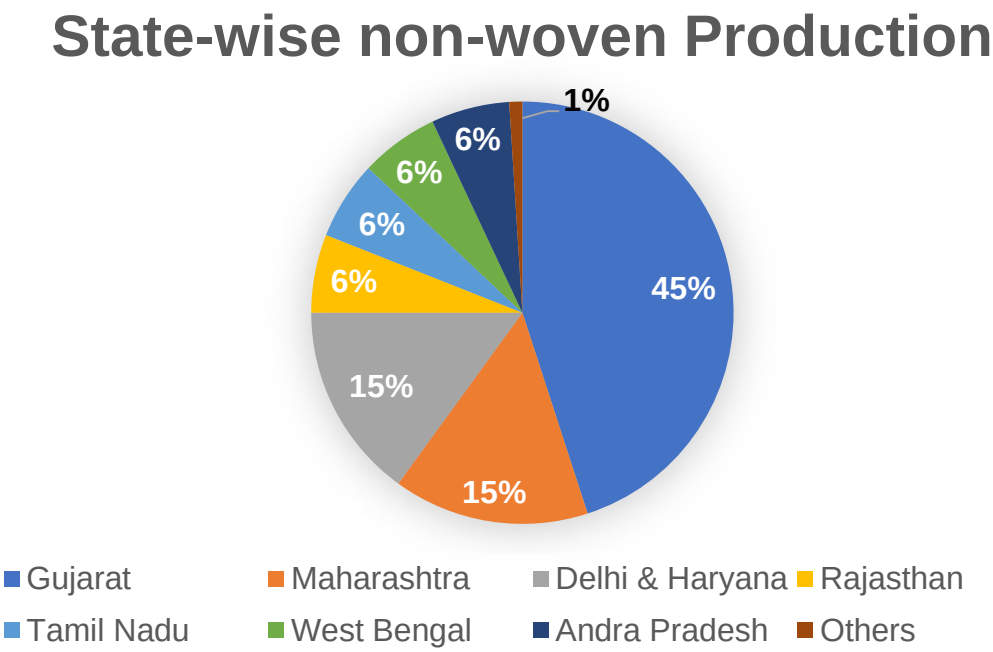
Asia is expected to maintain a CAGR of **11%** (tonnage consumption) through to 2018, the **highest** among all geographic regions.

India is 11th Largest market for US suppliers.

Key Reasons -
Growing Economies
Higher Disposable Incomes
Hygiene Consciousness

Nonwoven – India market Potential

- India's nonwoven market is growing at a rate of 8-10% & Going into the future this market is expected to grow at a rate of 12-15%
- Production of non-woven in India is estimated to be around 3.54 lakh MT for FY16
- During 2011-2016, the non-woven production grew at a CAGR of ~13%.
- There are nearly 50 nonwoven plants already existing in India.
- Gujarat is the hub for non-woven textile production in India, accounting for 45% of the total production. Maharashtra, Delhi and Haryana accounts for another 30% of the total production.



Growth Drivers – India

Packaging Industry:

The Indian packaging industry is likely to witness a annual growth of ~18% to reach US$73 billion by FY20

Automotive Industry:

India is aiming to increase the automobile production to 6 million cars annually. This will increase the demand for non-woven. Gujarat itself has 30 automobile clusters and likely to contribute 50% of the total automobile production in India by 2020.

Medical & Healthcare Industry:

The personal hygiene market is expected to grow at a CAGR of ~20% till FY20 primarily driven by rising disposable income and awareness among users. Growth of industry will create demand for non-woven

Geo-Textile Market:

For geo-textiles, export market has been the key driver for growth. This market is expected to grow at 15% per annum during 2015-2018 and is expected to reach INR12.8 billion by 2018.

Disposables & Durables

Nonwovens

Disposables

(Single use or short life use)

- **Wipes** (*baby wipes, personal care wipes, industrial wipes, household wipes*)

- **Medical** (*surgical drapes and gowns, instrument wraps, bandages, sponges*)

- **Baby Diapers**
- **Feminine Hygiene**
- **Adult Incontinence**

(*Topsheet, Backsheets, absorbent core*)

Durables

(Multiple use or long term use)

- Filtration
- Automotive
- Geotextiles
- Agriculture
- Work/Protective Wear
- Coating Substrates
- Shoe Inserts
- Interlinings
- Artificial Leather Backing

Market Segments – Disposable Nonwovens

Hygiene

- Baby Diapers
- Fem-Care
- Adult Incontinence

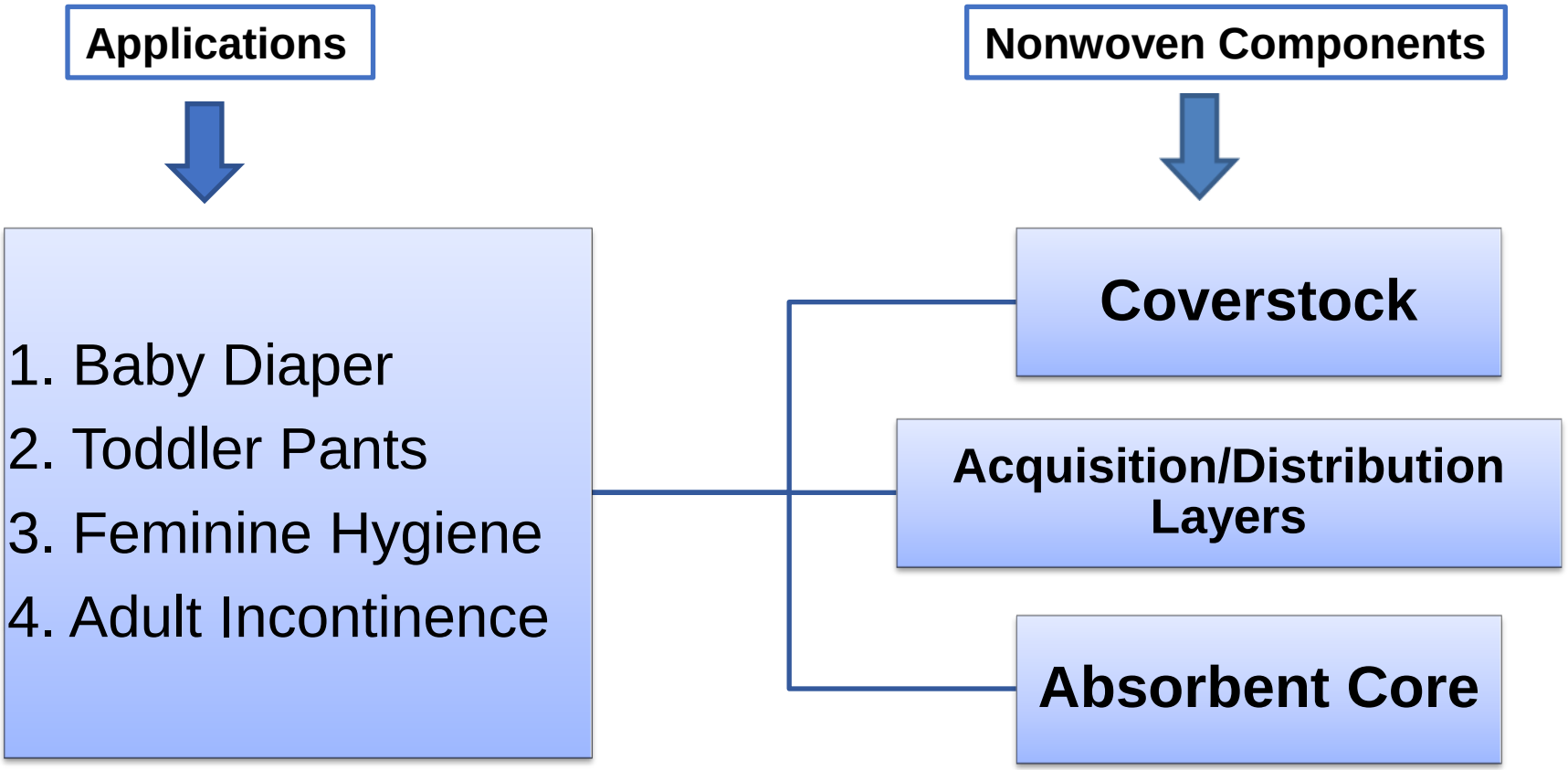
Medical

- Surgical Drapes
- Surgical Gowns
- Instrument Wraps
- Bandages
- Sponges

Hygiene . . .

Hygiene

Hygiene market is the largest consumer of disposable nonwovens and is expected to grow at above average rates through to 2020.



Hygiene

Figure 1 Schematic Overview of a Modern Disposable Diaper

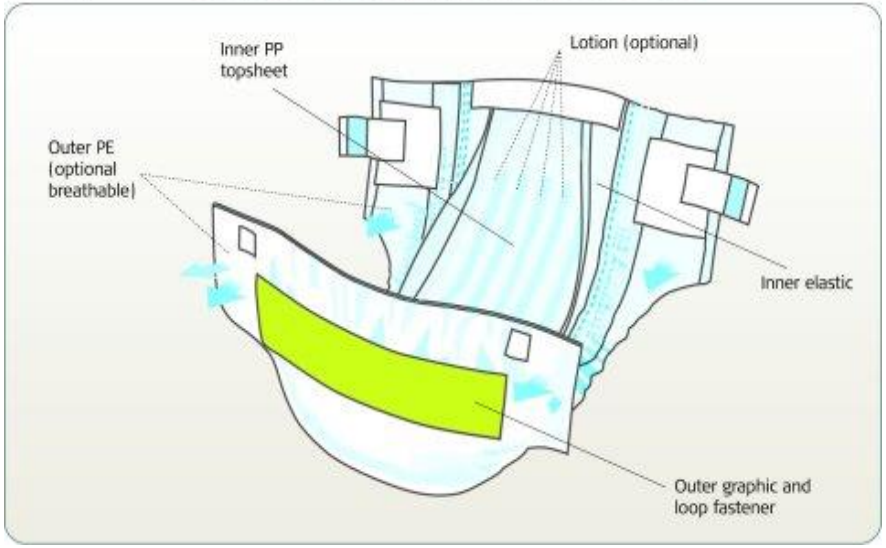


Figure 2 Schematic View of a Belted Incontinence Product

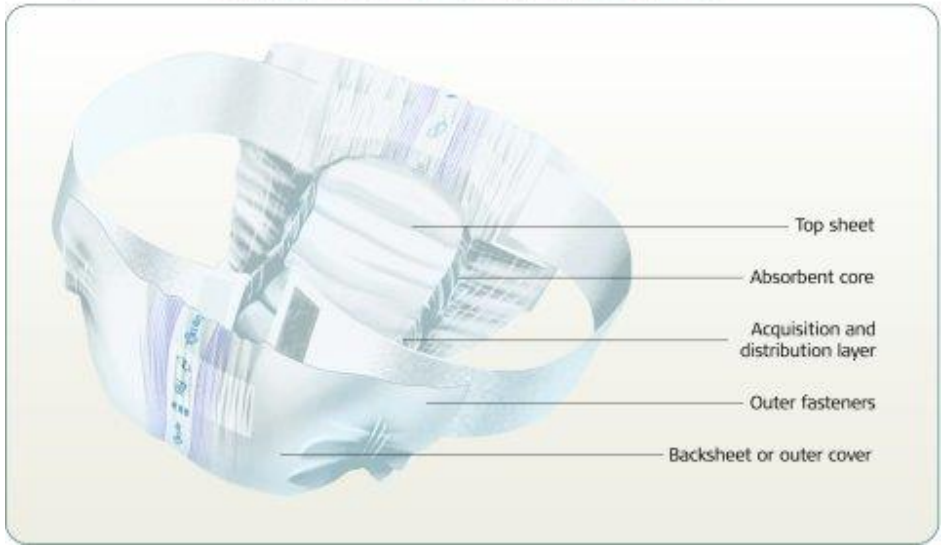


Figure 3 Schematic View of an Ultrathin Sanitary Pad

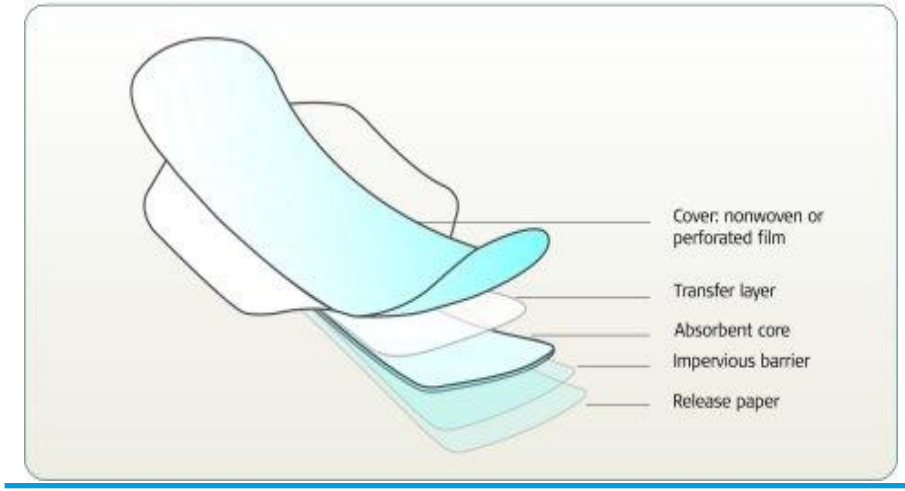
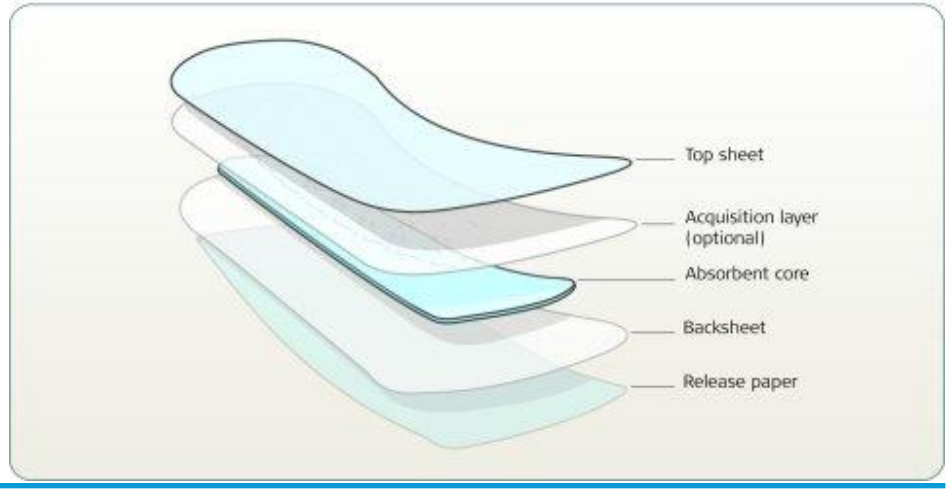
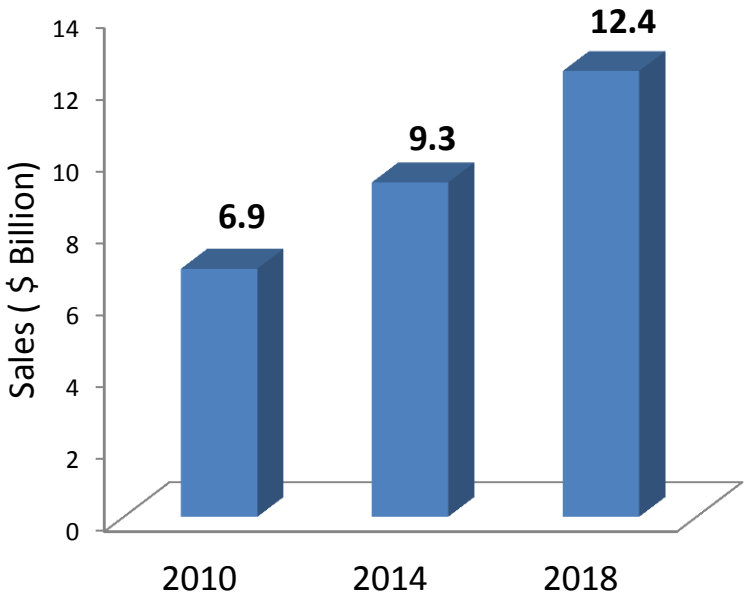


Figure 4 Schematic View of a Pantyliner



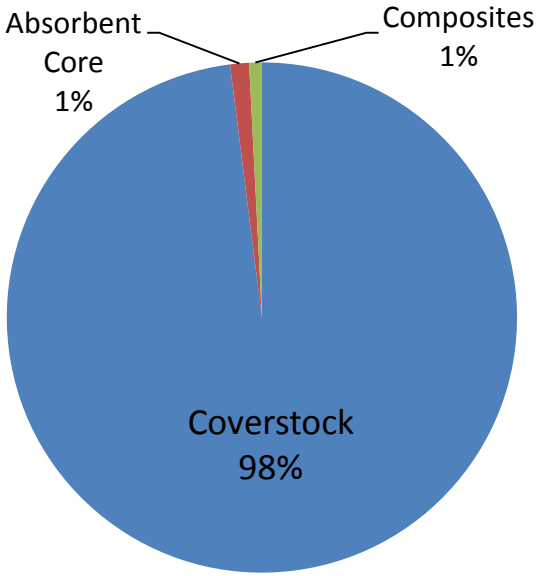
Market Overview

Hygiene Nonwovens Sales



- *Sales CAGR is projected to be 7.5% for '14-'20, up from 6.6% for 10'-14'.*
- *Tonnage Consumption is expected to grow to $ 2.9 mn in 2020*

Component Distribution (Sqm)



Although Hygiene market is 'Mature' in most developed markets, the base volumes are still large.

Coverstock

Major End-use Consumption:

- *Infant Diapers*
- *Toddler Training Pants*
- *Feminine Hygiene Pads*
- *Adult Incontinence*

Material Composition - Synthetic Nonwovens:

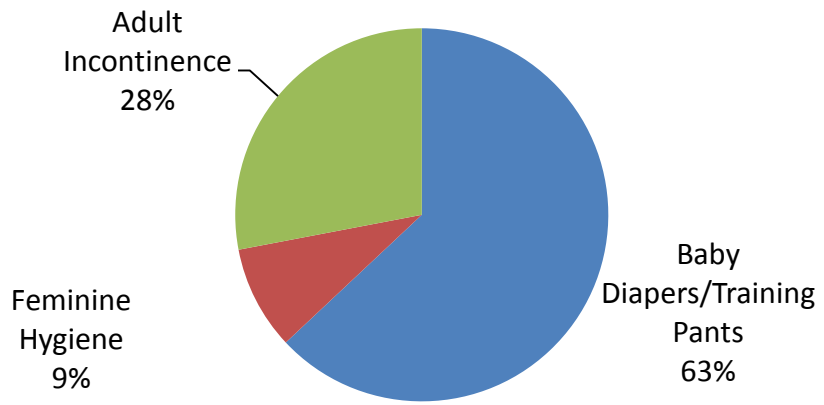
- *Spunbond Polypropylene*
- *Carded Polyester*
- *SMS (Spunbond/Meltblown/Spunbond)*

(Basis Weight – Average 19 GSM and Lowest 9 GSM)

Components that use Coverstock:

- *Topsheet (Skin Contact Material)*
- *Barrier Leg & Waist Cuffs (Diapers)*
- *Side Panels*
- *Cloth-like Backsheets*
- *Fastening Strips*

Coverstock Consumption

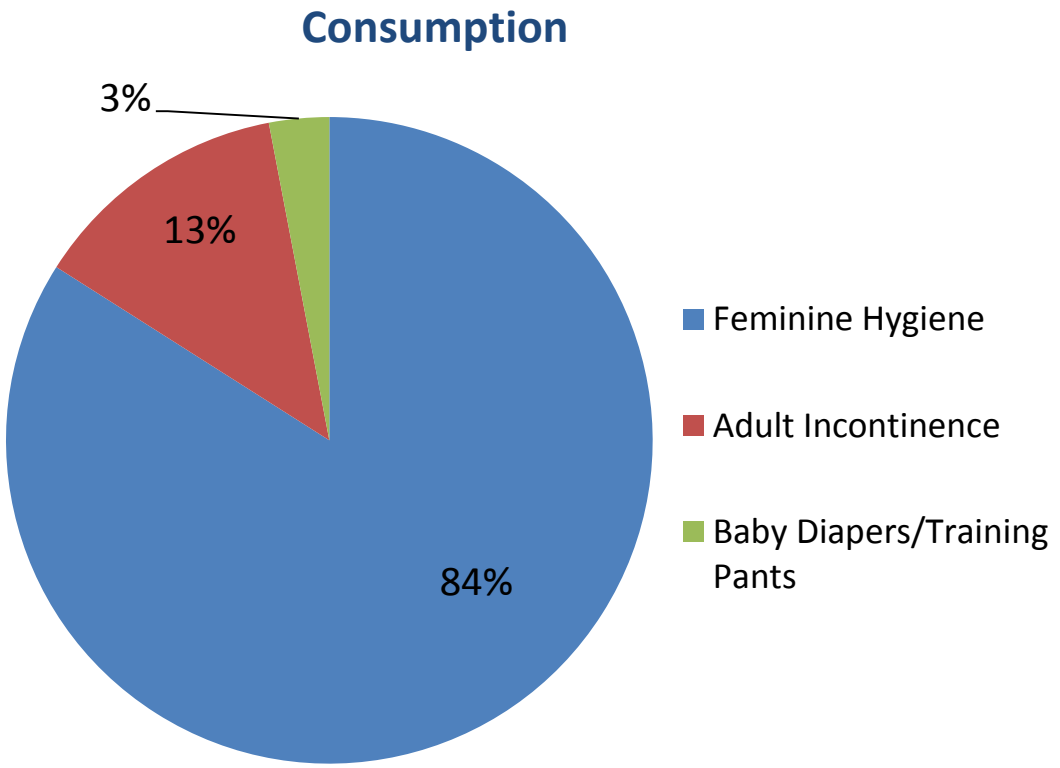


CAGR for Coverstock is projected to be 5.5% (sqm) for 2013-2020 with Adult Continence having the highest CAGR of 6.8%, ahead of Diapers (4.4%) and Fem-Hygiene (5%).

Absorbent Core & Acquisition/Distribution Layers

Material Composition – Airlaid Pulp Nonwovens

- *Feminine Hygiene Ultrathin Pads (120 – 300 GSM)*
- *Pantyliners (60 – 90 GSM)*
- *Feminine Hygiene ADL (60 – 80 GSM)*



CAGR for Airlaid Nonwovens in Hygiene is projected at 6.9% from 2013-2020

Future Trends

Biggest trends in Hygiene are to move to lighter-weight Coverstock through:

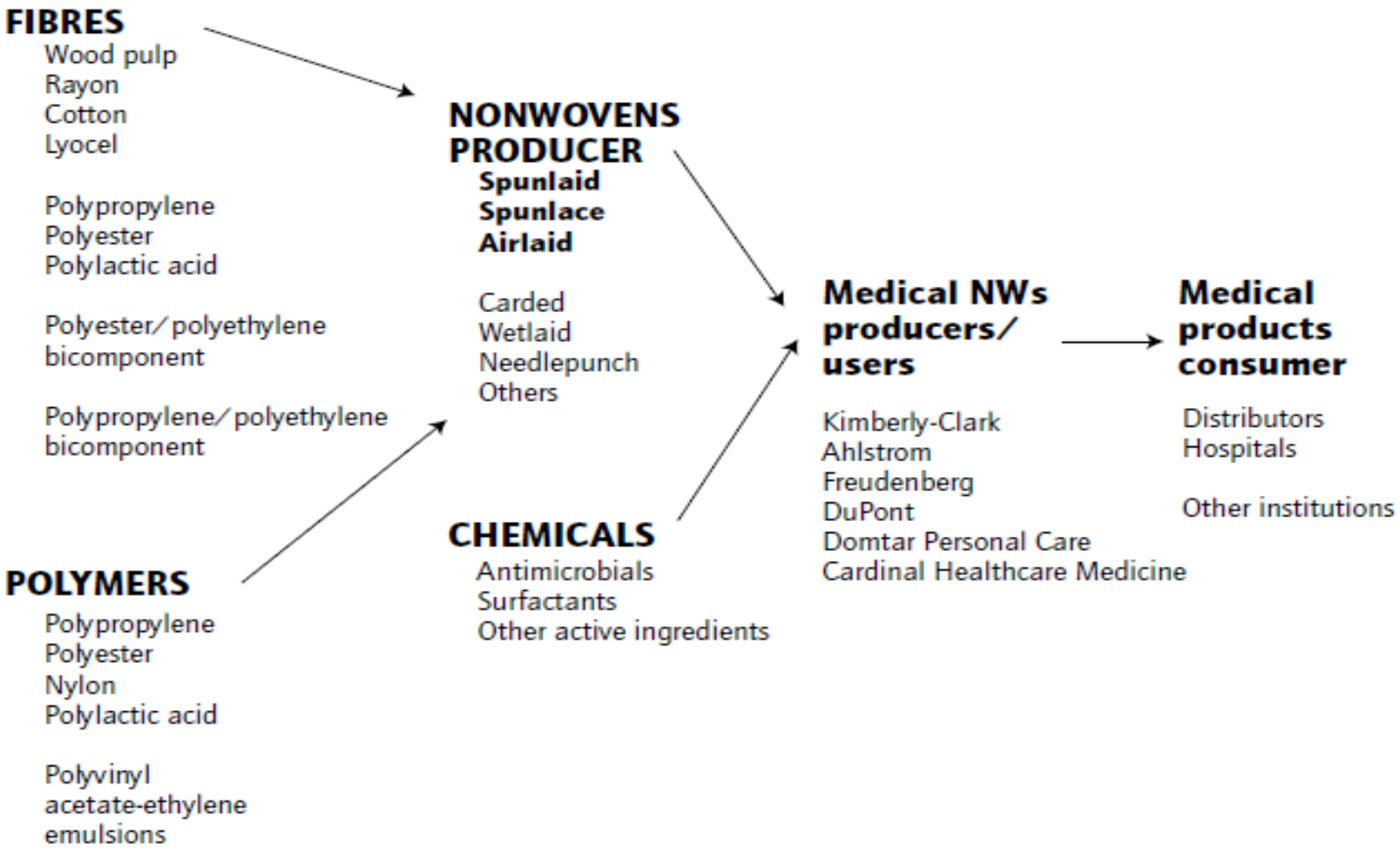
- *Step change improvements in Spunbond equipment*
- *Increasing use of Airlaid Nonwovens*
- *Thinner, more discrete, higher performance products*

These trends are driven by market demands from a larger, more affluent and physically active segment of the population.

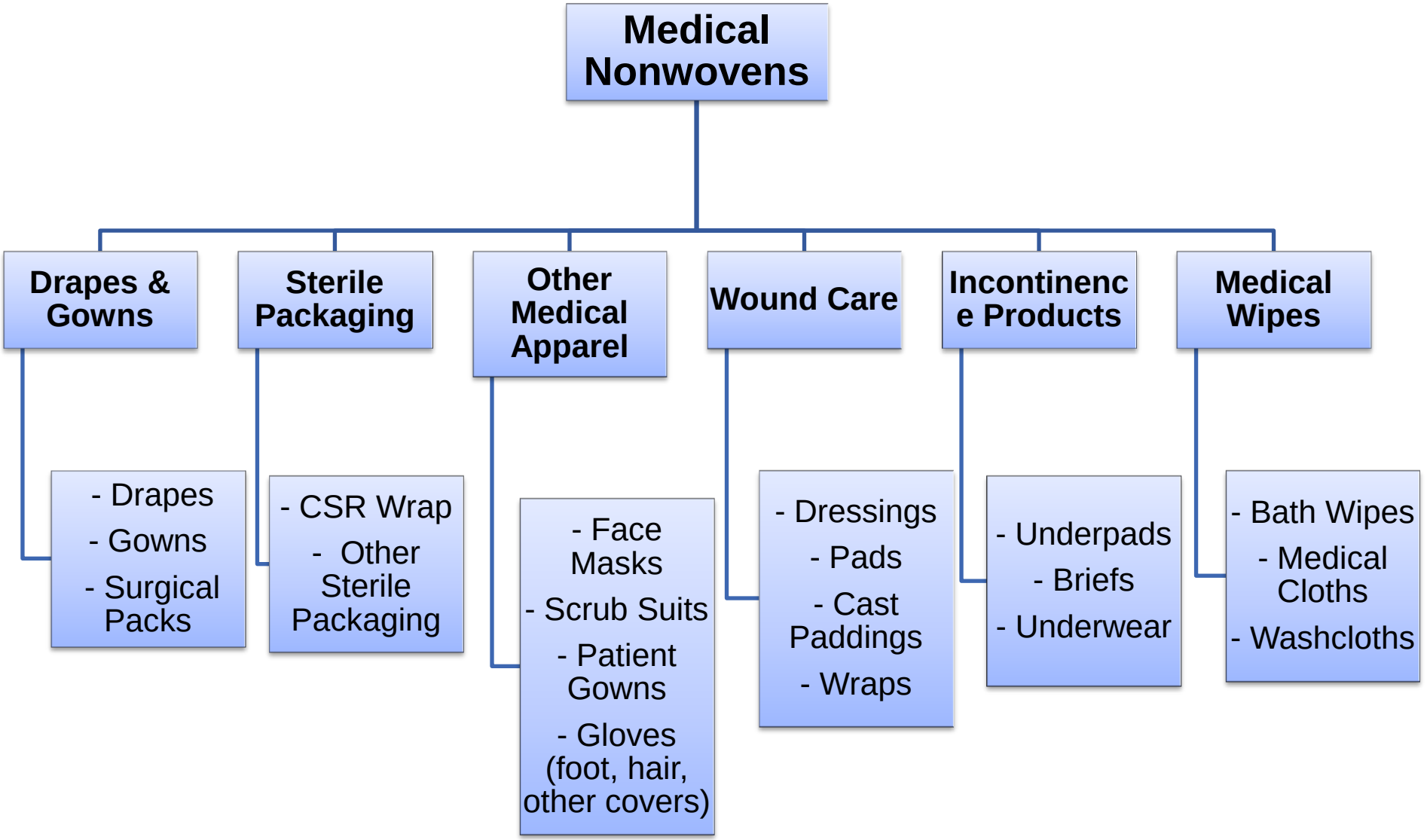
Although Hygiene is a mature market in developed economies, in developing regional markets of China and India that are just beginning to use Hygiene products, the growth is rapid.

Medical . . .

Medical – Supply Chain

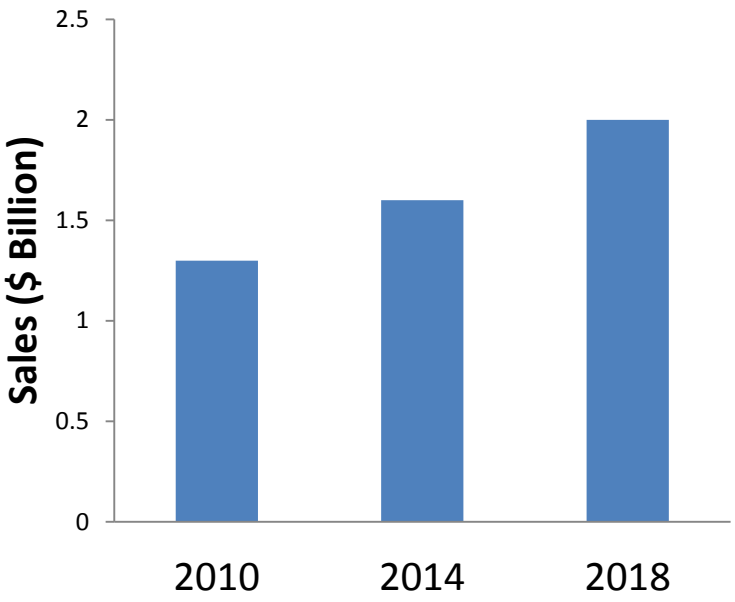


Medical – Product Categories



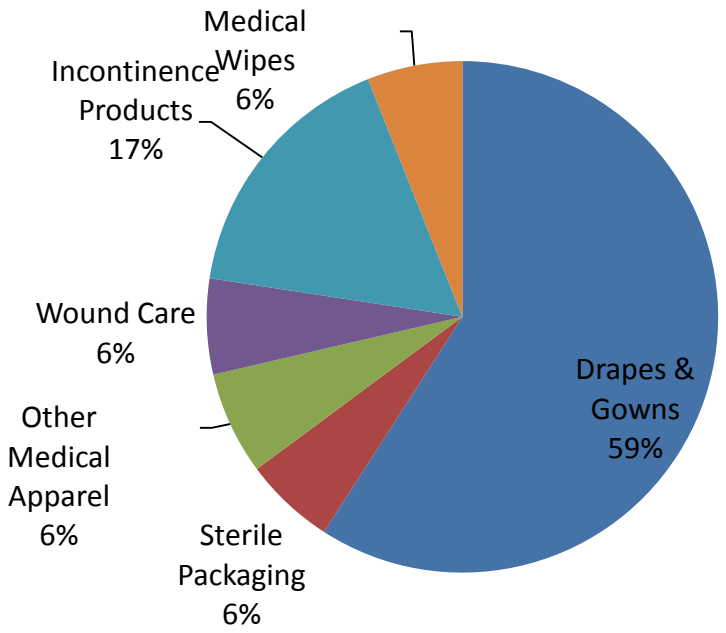
Market Overview

Medical Nonwoven Market



Sales projected to grow at a CAGR of 5.1% with tonnage consumption at a CAGR of 6.2%

End-use Sales Break-up



- ***Surgical Drapes & Gowns is the largest medical nonwovens globally.***
- ***Incontinence products are the 2nd largest and the fastest growing.***
- ***Wound Care is the next fastest growing.***

Market Drivers

Major Drivers for Medical Nonwovens Market:

- *Continuing replacement of **Reusable** (textile-based) medical fabrics by **Disposable** (nonwoven based) medical fabrics.*
- *Increasing responsibility of Hospitals and Institutions for **Hospital Acquired Infections** (HAIs).*
- *Increasing emphasis on **Cost Control** for Healthcare.*
- *Increasing potential for **Pandemic Outbreaks** (SARS, Avian Influenza, Swine Flu etc)*
- *Increasing need for **Assisted care** and **incontinence** products.*
- *Growing availability of modern healthcare to **Emerging Market** regions*

Medical Devices Rules

INDIA – Medical device industry

The Indian medical device market valued at US$3.5 billion in 2015 and could expand to approximately US $4.8 billion by 2019.

As India's economic, healthcare, and social landscapes evolve, its medical device market emerges as a promising opportunity.

Opportunities in the Indian market:

- India relies on imports to supply its healthcare system with medical technology.
- The medical tourism and luxury healthcare markets are among India's fastest-growing industries,
- Demand for specialized, high-tech medical equipment.

Industry challenges in India:

- Medical device regulation in India only apply to certain product categories.
- The weak rupee makes it difficult for some medical device companies to remain profitable in this market, particularly for manufacturers competing with low-cost Chinese products.
- Significant competition from American, European, and Japanese companies.

India compares to other markets

	INDIA	Compare to UNITED STATES	Compare to CHINA
Population	1,25 Billion	0. 32 Billion	1,36 Billion
Primary language(s)	Hindi	English	Chinese, Mandarin
Total healthcare spending	$93 billion	$3000 Billion	$574 billion
Healthcare expenditures total (% of GDP)	4.7%	17.1%	5.5%
Healthcare expenditures per capita	$75 (USD)	$9403 (USD)	$420 (USD)
Expenditures on healthcare	Government: 30% Private: 70%	Government: 48% Private: 52%	Government: 56% Private: 44%
Size of medical device market (USD)	$3.5 billion (USD)	$147.7 billion (USD)	$8.7 billion (USD)
Number of hospital beds	0.7 per 1000 people	2.9 per 1000 people	3.8 per 1000 people
Age distribution	0-14 years: 28% 15-64 years: 66% 65 years and over: 6%	0-14 years: 19% 15-64 years: 66% 65 years and over: 15%	0-14 years: 17% 15-64 years: 73% 65 years and over: 10%
Life expectancy at birth	Male: 67 years Female: 69 years	Male: 77 years Female: 82 years	Male: 73 years Female: 78 years
Currency	Rupee	US dollar ($)	Renminbi yuan (￥)

Table 4: Industry Profile 1 (All estimated values in Rs. Crore)

	Total Sales (Import + Indigenous)	Percentage share of the Total Sales (%)	Indigenous Sales Rs.	Percentage (%)	Imports	Percentage (%)
Disposables & Consumables	9,650	31.3	6,500	67.3	3,150	32.7
Medical Electronics, Hospital Equipment, Surgical Instruments	16,600	53.7	2,100	12.6	14,500	87.4
Implants	2,200	7.1	450	20.5	1,750	79.5
Diagnostics Reagents	2,450	7.9	550	22.5	1,900	77.5
Total	**30,900**	**100**	**9,600**		**21,300**	

Source : AIMED

Export of Medical Devices in India

(All values in Rs. Crore)

S No.	Description / HS Code	2011-12	2012-13	2013-14
1	Disposables and Consumables (HS Code 9018, 9020, 9021, 9027, 3006, 4818)	1 ,414.78	1,820.06	2,719.73
2	Electronics & Equipment (HS Code 9018, 9019, 9021, 9022, 9027, 9402)	1,934.86	2,174.37	2,797.34
3	Implants (HS Code 9018, 9021)	92.61	138.95	178.96
4	Surgical Instruments (HS Code 9018)	606.18	625.05	777.70
5	IVD Reagents (HS Code 3006, 3822)	136.63	187.42	279.08
	GRAND TOTAL	**4,185.06**	**4,945.84**	**6,752.82**

Medical Devices Rules

1. USA
2. EUROPE
3. INDIA

USA

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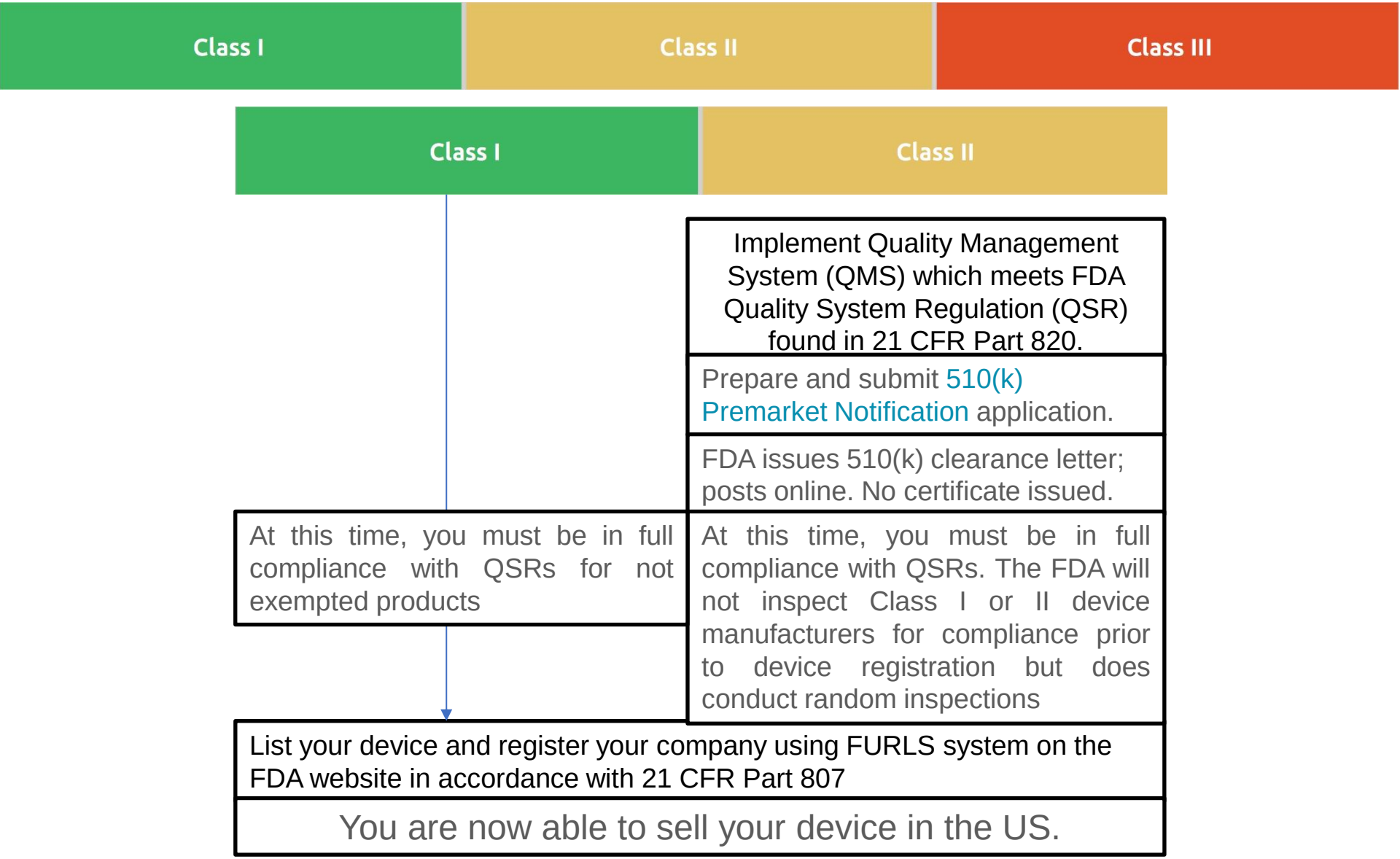
Determine the classification of your device by searching the FDA classification database



EUROPE

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ADVANCED TEXTILES

To obtain CE Marking certification, you must comply with European Commission Regulation (EU) No. 2017/745, commonly known as the Medical Device Regulation (MDR).

Class I Self-certified	Class I Sterile, measuring or reusable surgical	Class IIa	Class IIb	Class III

EUROPE

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ADVANCED TEXTILES

Class I Self-certified	Class I Sterile, measuring or reusable surgical
Implement QMS. Notified Body intervention is not required	Implement a Quality Management System (QMS) in accordance with the MDR. Most companies apply the EN ISO 13485 standard to achieve compliance. Your QMS must include Clinical Evaluation, Post Market Surveillance (PMS) and Post Market Clinical Follow-up (PMCF) plans. Make arrangements with suppliers about unannounced Notified Body audits.
Prepare CE Technical File with CER according to Annex II and III.	In accordance with Annex II and III, prepare a CE Technical File or Design Dossier (Class III*) providing information about your device and its intended use plus testing reports, Clinical Evaluation Report (CER), risk management plan, IFU, labeling and more. Obtain a Unique Device Identifier (UDI) for your device.
No Notified Body audit of QMS or Technical File.	Your QMS and Technical File or Design Dossier must be audited by a Notified Body, a third party accredited by a European Competent Authority to audit quality management systems and products.
	You will be issued a CE Marking certificate for your device and an ISO 13485 certificate for your facility following successful completion of your Notified Body audit. ISO 13485 certification must be renewed every year. CE Marking certificates are valid for a maximum of 5 years, but are typically reviewed during your annual surveillance audit.
Prepare a Declaration of Conformity in accordance with Annex IV, a legally binding document prepared by the manufacturer stating that the device is in compliance with applicable European requirements. You may now affix the CE Marking.	
Register the device and its Unique Device Identifier (UDI) in the EUDAMED database. UDI must be on label.	
Clinical evaluation and technical file must be kept updated.	You will be audited by a Notified Body each year to ensure ongoing compliance with the MDR. Failure to pass the audit will invalidate your CE Marking certificate. Your must perform Clinical Evaluation, PMS and PMCF activities to maintain certification.

It is Covered covered under underd Drugs and Cosmetics Act.

Step 1

Is your product on the list below of Notified Medical Devices and IVDs which require device registration in India.

1. Blood Component Bags,
2. Blood Grouping Sera,
3. Bone Cements,
4. Cardiac Stents,
5. Catheters, Condoms,
6. Disposable Hypodermic Needles,
7. Disposable Hypodermic Syringes,
8. Disposable Perfusion Sets,
9. Drug Eluting Stents,
10. Heart Valves, IV Cannulae,
11. Internal Prosthetic Replacements,
12. Intra Ocular Lenses,
13. Intra Uterine Devices,
14. IVD Devices for HIV,
15. HBsAG and HCV,
16. Orthopedic Implants,
17. Scalp Vein Sets,
18. Skin Ligatures,
19. **Surgical Dressings,**
20. Sutures and Staplers,
21. Tubal Rings,
22. Umbilical Tapes

Step 2
For medical device or IVD on list above, file application for Device Registration Certificate to CDSCO using Form 40. Schedules D-1 and D-2 must be included, as well as verification of compliance with US, Canadian, European, Japanese or Australian medical device regulations.

Step 3
For medical device or IVD on list above, device manufacturers new to India required Form 45 (New Drug License) in support of the Form 40 application.

Step 4
For medical device or IVD on list above, obtain Registration Certificate Form 41 from CDSCO. Certificate is valid for up to 3 years.

Step 5:
License valid for 3 years.

Step 6
You are now authorized to market your device in India.

Medical Device Rules, 2017

Medical Device Rules, 2017

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- Demand to separate the medical device industry from the pharmaceutical industry.

- In January 2017, the Ministry of Health and Family Welfare of India published the Medical Device Rules, 2017.
- The new rules will go into effect on January 1, 2018.

- Medical devices have been divided into four categories based on their risk type.
  1. Low (Class A)
  2. Low Moderate (Class B)
  3. Moderate High (Class C)
  4. High (Class D)

The method of classification is described in detail in the first schedule of the 2017 Rules.

Medical Device Rules, 2017

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Unique features

- Licenses will remain valid until they are suspended, cancelled or surrendered.
- Will be managed via an online electronic platform.
- Timelines have been defined for most activities at the regulator's end.

Create a robust eco-system for all stakeholders including innovators, manufacturers, providers, consumers, buyers and regulators.

Medical Device Rules, 2017

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	Class A	Class B
Self-certify	Yes	Yes
Official inspection	No	No
Prior audit by third party*	No	Yes
Quality Management System will need to be aligned with ISO 13485	Yes	Yes
Verification and assessment of the Quality Management Systems	Need Base	Yes
Single window clearance	Yes	Yes

*Third Party Conformity Assessment and Certification" through Notified will be accredited by the National Accreditation Board for Certification Bodies (NABCB).

Medical Device Rules, 2017

WELSPUN INDIA
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	USA		Europe		INDIA	
Level	I	II	Class I Self Certi	Class I	Class A	Class B
Self-certify	Yes	Yes	Yes	NO	Yes	Yes
Official inspection	No	No	No	Yes	No	No
Prior audit by third party*	No	NO	NO	Yes	No	Yes
Quality Management System will need to be aligned with ISO 13485	Some are exempted	Yes	Yes	Yes	Yes	Yes
Verification and assessment of the Quality Management Systems	Random	Random	No	Yes	Need Base	Yes
Single window clearance					Yes	Yes
List Device	Yes	Yes	Yes	Yes	Yes	Yes
UDI	NO	NO	Yes	Yes	Yes	Yes
Expire	NO	No	NA	5 Year	No	No

Recommendations:

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1. Exempts Nonwoven Medical Devices (Class A & B) similar to FDA
   FDA exempted Class II Nonwoven medical devices from Premarket Notification.

List of Class II Medical Devices Exempt from 510(k) Requirements		
21 CFR	**FDA Device Type Description**	**Product Code**
872.3540	Pad, Denture, OTC	EHR
872.3540	Cushion, Denture, OTC	EHS
878.4370	Drape, Surgical, ENT.	ERY
878.4370	Drape, With Self-Retaining Finger Cot.	EYX
878.4370	Drape, Urological, Disposable	EYY
878.4370	Pad, Kelly	FNW
878.4370	Drape, Patient, Ophthalmic.	HMT
878.4370	Drape, Microscope, Ophthalmic.	HMW
878.4370	Ring Drape Retention, Internal.	KGW
878.4370	Drape, Surgical*	KKX
884.5425	Pad, Menstrual, Scented.	HHL
List of Class I Medical Devices Exempt from 510(k) Requirements		
21 CFR	**FDA Device Type Description**	**Product Code**
884.5435	Pad, Interlabial	NUR
*Exemption limited to drapes that do not include an antimicrobial agent. The Class II list also includes "crude" cotton and "treated" cotton fibers derived from the Gossypium genus of the plant (no specific CFR reference is included for either).		

2. BIS should follow system CE marking.
3. Product approved for BIS specification should automatically have the CE & vice versa
4. UDI (Unique Device Identity) system should be implemented from start

Recommendations:

4. Product Technical file should contain entire value chain details.

5. ASAP India should be party to IMDRF similar to Australia, Brazil, Canada, China, Europe, Japan, Russia, USA

6. This will help Indian Manufacturer exporter to Increase export of medical device – Disposable & Electronics

7. Regulation & Product Specification for Hygiene Products which are sold OTC

THANK YOU!