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

- **Raw Materials**
  - Chips (PP / PET)
  - Spun Melt
  - Melt Blown
  - SMS

- **Web Formation**
  - Spun Melt
  - SMS

- **Web Bonding**
  - Thermo Calendared
  - Chemical Bonding
  - Needling

- **Value Addition**
  - Calendar
  - Coating
  - Lamination

- **Conversion**
  - Cutting & Sewing
  - HF Welding
  - Ultrasonic Bonding

**High Value**
- Carding
  - Staple Fiber
  - Carding
  - Needling
  - Thermobond
  - Chemical
  - Spunlace

**Low Value**
- Spun Melt
- Chips (PP / PET)
- Melt Blown
- SMS
Global Consumption of Nonwovens

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
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.

State-wise non-woven Production

- Gujarat: 45%
- Maharashtra: 15%
- Delhi & Haryana: 15%
- Rajasthan: 15%
- Tamil Nadu: 6%
- West Bengal: 6%
- Andhra Pradesh: 6%
- Others: 1%
# 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.*

### Applications
1. Baby Diaper
2. Toddler Pants
3. Feminine Hygiene
4. Adult Incontinence

### Nonwoven Components
- Coverstock
- Acquisition/Distribution Layers
- Absorbent Core
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**

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

Components that use Coverstock:

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

Material Composition - Synthetic Nonwovens:

- Spunbond Polypropylene
- Carded Polyester
- SMS (Spunbond/Meltblown/Spunbond) (Basis Weight – Average 19 GSM and Lowest 9 GSM)

Coverstock Consumption

- Baby Diapers/Training Pants 63%
- Feminine Hygiene 9%
- Adult Incontinence 28%

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

FIBRES
- Wood pulp
- Rayon
- Cotton
- Lyocell
- Polypropylene
- Polyester
- Polylactic acid
- Polyester/polyethylene bicomponent
- Polypropylene/polyethylene bicomponent

NONWOVENS PRODUCER
- Spunlaid
- Spunlace
- Airlaid
- Carded
- Wetlaid
- Needlepunch
- Others

CHEMICALS
- Antimicrobials
- Surfactants
- Other active ingredients

POLYMERS
- Polypropylene
- Polyester
- Nylon
- Polylactic acid
- Polyvinyl acetate-ethylene emulsions

Medical NWs producers/users
- Kimberly-Clark
- Ahlstrom
- Freudenberg
- DuPont
- Domtar Personal Care
- Cardinal Healthcare Medicine

Medical products consumer
- Distributors
- Hospitals
- Other institutions
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

<table>
<thead>
<tr>
<th></th>
<th>INDIA</th>
<th>Compare to UNITED STATES</th>
<th>Compare to CHINA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>1.25 Billion</td>
<td>0. 32 Billion</td>
<td>1.36 Billion</td>
</tr>
<tr>
<td>Primary language(s)</td>
<td>Hindi</td>
<td>English</td>
<td>Chinese, Mandarin</td>
</tr>
<tr>
<td>Total healthcare spending</td>
<td>$93 billion</td>
<td>$3000 Billion</td>
<td>$574 billion</td>
</tr>
<tr>
<td>Healthcare expenditures total</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(% of GDP)</td>
<td>4.7%</td>
<td>17.1%</td>
<td>5.5%</td>
</tr>
<tr>
<td>Healthcare expenditures per</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>capita</td>
<td>$75 (USD)</td>
<td>$9403 (USD)</td>
<td>$420 (USD)</td>
</tr>
<tr>
<td>Expenditures on healthcare</td>
<td>Government: 30%</td>
<td>Government: 48%</td>
<td>Government: 56%</td>
</tr>
<tr>
<td></td>
<td>Private: 70%</td>
<td>Private: 52%</td>
<td>Private: 44%</td>
</tr>
<tr>
<td>Size of medical device market</td>
<td>$3.5 billion (USD)</td>
<td>$147.7 billion (USD)</td>
<td>$8.7 billion (USD)</td>
</tr>
<tr>
<td>(USD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of hospital beds</td>
<td>0.7 per 1000 people</td>
<td>2.9 per 1000 people</td>
<td>3.8 per 1000 people</td>
</tr>
<tr>
<td>Age distribution</td>
<td>0-14 years: 28%</td>
<td>0-14 years: 19%</td>
<td>0-14 years: 17%</td>
</tr>
<tr>
<td></td>
<td>15-64 years: 66%</td>
<td>15-64 years: 66%</td>
<td>15-64 years: 73%</td>
</tr>
<tr>
<td></td>
<td>65 years and over: 6%</td>
<td>65 years and over: 15%</td>
<td>65 years and over: 10%</td>
</tr>
<tr>
<td>Life expectancy at birth</td>
<td>Male: 67 years</td>
<td>Male: 77 years</td>
<td>Male: 73 years</td>
</tr>
<tr>
<td></td>
<td>Female: 69 years</td>
<td>Female: 82 years</td>
<td>Female: 78 years</td>
</tr>
<tr>
<td>Currency</td>
<td>Rupee</td>
<td>US dollar ($)</td>
<td>Renminbi yuan (¥)</td>
</tr>
<tr>
<td></td>
<td>Total Sales (Import + Indigenous)</td>
<td>Percentage share of the Total Sales (%)</td>
<td>Indigenous Sales Rs.</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------------------------------</td>
<td>----------------------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Disposables &amp; Consumables</td>
<td>9,650</td>
<td>31.3</td>
<td>6,500</td>
</tr>
<tr>
<td>Medical Electronics,</td>
<td>16,600</td>
<td>53.7</td>
<td>2,100</td>
</tr>
<tr>
<td>Hospital Equipment,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical Instruments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implants</td>
<td>2,200</td>
<td>7.1</td>
<td>450</td>
</tr>
<tr>
<td>Diagnostics Reagents</td>
<td>2,450</td>
<td>7.9</td>
<td>550</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>30,900</strong></td>
<td><strong>100</strong></td>
<td><strong>9,600</strong></td>
</tr>
</tbody>
</table>

*Source: AIMED*
## Export of Medical Devices in India

(All values in Rs. Crore)

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

1. USA
2. EUROPE
3. INDIA
Determine the classification of your device by searching the FDA classification database

<table>
<thead>
<tr>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
</tr>
</thead>
</table>

List your device and register your company using FURLS system on the FDA website in accordance with 21 CFR Part 807

You are now able to sell your device in the US.

Class I

- Implement Quality Management System (QMS) which meets FDA Quality System Regulation (QSR) found in 21 CFR Part 820.
- Prepare and submit 510(k) Premarket Notification application.
- FDA issues 510(k) clearance letter; posts online. No certificate issued.

At this time, you must be in full compliance with QSRs for not exempted products.

Class II

- At this time, you must be in full compliance with QSRs. The FDA will not inspect Class I or II device manufacturers for compliance prior to device registration but does conduct random inspections.

Class III
To obtain CE Marking certification, you must comply with European Commission Regulation (EU) No. 2017/745, commonly known as the Medical Device Regulation (MDR).
<table>
<thead>
<tr>
<th>EUROPE</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class I</strong>&lt;br&gt;Self-certified</td>
<td><strong>Class I</strong>&lt;br&gt;Sterile, measuring or reusable surgical</td>
</tr>
<tr>
<td>Implement QMS. Notified Body intervention is not required</td>
<td>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.</td>
</tr>
<tr>
<td>Prepare CE Technical File with CER according to Annex II and III.</td>
<td>In accordance with Annex II and III, prepare a <strong>CE Technical File or Design Dossier (Class III)</strong> 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.</td>
</tr>
<tr>
<td>No Notified Body audit of QMS or Technical File.</td>
<td>Your QMS and <strong>Technical File or Design Dossier</strong> must be audited by a Notified Body, a third party accredited by a European Competent Authority to audit quality management systems and products.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Register the device and its Unique Device Identifier (UDI) in the EUDAMED database. UDI must be on label.</td>
</tr>
<tr>
<td>Clinical evaluation and technical file must be kept updated.</td>
<td>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.</td>
</tr>
</tbody>
</table>
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 require 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.
• 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.
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.
<table>
<thead>
<tr>
<th></th>
<th>Class A</th>
<th>Class B</th>
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<tbody>
<tr>
<td>Self-certify</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Official inspection</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Prior audit by third party*</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Quality Management System will need to be aligned with ISO 13485</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Verification and assessment of the Quality Management Systems</td>
<td>Need Base</td>
<td>Yes</td>
</tr>
<tr>
<td>Single window clearance</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*Third Party Conformity Assessment and Certification” through Notified will be accredited by the National Accreditation Board for Certification Bodies (NABCB).
### Medical Device Rules, 2017

<table>
<thead>
<tr>
<th></th>
<th>USA</th>
<th>Europe</th>
<th>INDIA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level</strong></td>
<td>I</td>
<td>II</td>
<td>Class I</td>
</tr>
<tr>
<td><strong>Self-certify</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Official inspection</strong></td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Prior audit by third party</strong></td>
<td>No</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td><strong>Quality Management System will need to be aligned with ISO 13485</strong></td>
<td>Some are exempted</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td><strong>Verification and assessment of the Quality Management Systems</strong></td>
<td>Random</td>
<td>Random</td>
<td>No</td>
</tr>
<tr>
<td><strong>Single window clearance</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>List Device</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>UDI</strong></td>
<td>NO</td>
<td>NO</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Expire</strong></td>
<td>NO</td>
<td>No</td>
<td>NA</td>
</tr>
</tbody>
</table>
1. Exempts Nonwoven Medical Devices (Class A & B) similar to FDA
   FDA exempted Class II Nonwoven medical devices from Premarket Notification.

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
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!