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Product:	Gauze Product, Sterile
Intended Use	Wound cleansing, skin cleansing e.g. before a surgical operation, and absorption of exudates.
Doc ref	PD-020042
<b>Product Classification according to Annex IX MDD (if applicable):</b>	
Class	I
Classification rule applied:	Rule 4 – first indent
Remarks:	Non-invasive medical device which comes into contact with injured skin to absorb and protect the wound

<b>Product Classification according to FDA (if applicable)</b>			
Class	1	510(k) Required	No
Regulation Number: <small>(e.g. 878.4040)</small>	878.4018		
Classification Code: <small>(e.g. FXY)</small>	NAC		
Remarks:			
<b>Other Classification (if applicable)</b>			
According to:			
Class			
Remarks:			

**These claims are not applicable to the US market without internal US regulatory approval.**

<b>Material properties:</b>	<b>Doc. reference</b>
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Material properties <ul style="list-style-type: none"> <li>• 100% cotton</li> <li>• Bleached without chlorine</li> <li>• Without binding agents</li> <li>• Absorbent</li> <li>• Softness</li> </ul>	EN 14079
Silicone ring (If applicable) <ul style="list-style-type: none"> <li>• Elastic</li> <li>• Free from natural rubber latex</li> </ul>	PD-015153

<b>Functional properties:</b>	<b>Doc. reference</b>
• Absorption of wound exudates	1, 2
• Absorption of blood	1, 2
• Protection against external trauma	1, 2
• Cleansing of skin and wound	1, 2
• Non sensitising	1, 3
• Non toxic	1, 3

<b>Doc. References:</b>
<ol style="list-style-type: none"> <li>1. Post Marketing Surveillance Reports Gauze</li> <li>2. Clinical Evaluation, PD-390672</li> <li>3. Biocompatibility Evaluation, PD-020826</li> </ol>

## Summary

Describes the correlation between claims and references

### 1. Absorption of wounds exudates

Ref.1 This functional property is based on the experience of having Gauze on the market for the last 20 years.

Ref.2 Clinical Evaluation includes references to literature supporting this functional property.

### 2. Absorption of blood

Ref.1 This functional property is based on the experience of having Gauze on the market for the last 20 years.

Ref.2 Clinical Evaluation includes references to literature supporting this functional property.

3. Protection against external trauma

Ref.1 This functional property is based on the experience of having Gauze on the market for the last 20 years.

Ref.2 Clinical Evaluation includes references to literature supporting this functional property.

4. Cleansing of skin and wound

Ref.1 This functional property is based on the experience of having Gauze on the market for the last 20 years.

Ref.2 Clinical Evaluation includes references to literature supporting this functional property.

5. Non sensitising

Ref.1 This functional property is based on the experience of having Gauze on the market for the last 20 years.

Ref.3 Biocompatibility Evaluation shows that Gauze is non-sensitising and non-irritating. Approved Biocompatibility PD-020826

6. Non toxic

Ref.1 This functional property is based on the experience of having Gauze on the market for the last 20 years.

Ref.3 Biocompatibility Evaluation shows that Gauze is non-toxic. Approved Biocompatibility PD-020826