

**PRODUCT SPECIFICATION**

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|---------------------|---|
| <b>Product name</b> | Tongue Depressor  |
| <b>Range</b>        | Universal   |
| <b>Type</b>         | Non-sterile   |
| <b>Marking</b>      | Product name, Universal logo, code ref, lot number, CE mark, expiry date, latex free, and single use symbols. |
| <b>Material</b>     | Wood (Natural Birch)  |
| <b>Dimensions</b>   | 150x17mm  |



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| <b>Primary use</b> | Intended to be used to depress the tongue to allow for examination of the mouth and throat. |
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| PACKAGING |                                |  |
|-----------|--------------------------------|--|
| MOQ       | Inner Box Configuration        | Outer Case   |
| 5000pcs   | 100pcs<br>Box Size 150x87x35mm | 50 inner cases of 100pcs<br>Box Size 445x155x360mm |

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| <b>Conformity to Regulations</b>   | European Medical Device Regulation 2017/745                  |
| <b>Device Classification</b>   | Class I  |
| <b>Conformity to standards</b>   | ISO 13485:2016   |
| <b>Storage conditions</b>  | Store in a cool dry place away from heat and direct sunlight |
| <b>Shelf life</b>  | 5 Years- if stored as recommended above                      |
| <b>Additional information</b>  | Latex free   |
| <i>Medical Device and Reporting System:<br/>Incidents caused by this device must be reported immediately to our offices.</i> |  |

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| <b>REVISION:</b> | 5.0 | <b>DATE</b> | 03/06/2020 | <b>AUTHOR</b> | A Gidley |
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The information provided within this Data Sheet is correct as of last revision but it is subject to change without notice.

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