

REF No.: ECD0C-SD/01/140219

## EC DECLARATION OF CONFORMITY

|                                     |   |
|-------------------------------------|---|
| <b>Manufacturer:</b>                | Curas Ltd. (RO)<br>69A-B, Raja Uda Business Centre Road 4<br>12300 Butterworth, Penang<br>Malaysia                        |
| <b>Authorized Representative:</b>   | Curas Ltd.<br>County Gates, Ashton Road<br>Bristol BS3 2JH<br>England   |
| <b>Medical Device(s):</b>           | Hygiene Pulp™ Disposable Moulded Pulp Products<br>Hygiene Pulp™ Disposable 100% Pure Pulp<br>(Non-Sterile)                |
| <b>Classification:</b>              | Class I, according to Annex IX, Rule I of Council Directive 93/42/EEC, as amended by Directive 2007/47/EC                 |
| <b>Conformity Assessment Route:</b> | Self-declaration that the products meet the provisions of Council Directive 93/42/EEC, as amended by Directive 2007/47/EC |
| <b>Standards Applied</b>            | EN ISO 13485:2016, MDD/93/42/EEC, PAS 29:1999   |

We hereby declare that the abovementioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained at the premises of the manufacturer and its authorized representative.

**Authorised Signatory:**



**Name:** Casper Kobke

**Position:** Managing Director

**Date:** 14 February 2019

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