


**Declaration of confirmity Skin-Elast-Hook**

**Declaration of Conformity**

According Annex I of guideline 93/42/EWG

For following article:

**Skin-Elast-Hook**

|   |   |
|---|---|
| <b>Name &amp; address</b>               | <p align="center"><b>CMD GmbH</b><br/>4652 Fischlham, Gewerbepark 5</p>   |
| <b>Article name and classification:</b> | <p align="center"><b>Skin-Elast-Hook</b><br/><b>14299W0-B, 14299W0-G (Skin-Elast-Hook-LARGE)</b><br/><b>15097W0-B, 15097W0-G (Skin-Elast-Hook-SMALL)</b><br/><b>class IIa sterile</b></p>   |
| <b>Declaration of conformity</b>        | <p>The above mentioned article complies with the basic requirements of Annex I of guideline 93/42/EWG, section 7<br/>The evaluation procedure was conducted according to Annex V of guideline 93/42/EWG.</p>  |
| <b>Applied standards</b>                | <p>The articles will be prepared in line with following standards and guidelines:<br/> <b>EN ISO 13485:</b> Medical devices – quality management systems – requirements for regulatory purposes<br/> <b>EN ISO 14971:</b> Medical devices – Application of risk management for medical devices<br/> <b>EN ISO 15883-1:</b> RDG-general requirements<br/> <b>EN ISO 11607-1:</b> Packaging for sterilization inside of final packaging<br/> <b>EN 15223-1:</b> Symbols for labelling of medical devices; labelling and documentation<br/> <b>EN ISO 11135-1:</b> Sterilization of articles for health care applications – ethylene oxide<br/> <b>EN ISO 11737-1:</b> Sterilization of medical devices – microbiological procedure<br/> <b>EN ISO 10993-1:</b> biological evaluation of medical devices -Part 1 evaluation and testing<br/> <b>EN ISO 10993-7:</b> Biological evaluation -of medical devices; remaining gas examination</p> |
| <b>CE-marking</b>                       | <p align="center"><b>CE 0483</b></p>  |
| <b>Notified body</b>                    | <p align="center">mdc medical device certification GmbH<br/>D-70191 Stuttgart, Kriegerstraße 6</p>  |

The declaration of conformity was issued in sole responsibility of the company mentioned above. Validity: 3 years

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Managing director

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 Erstellt: Hr. R. Köttner  
 Geprüft/Freigegeben: Hr. Ch. Hefner  
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