

# EG-Declaration of Conformity

according to the EG directive medical devices 93/42/EGW, Annex VII

## The production of the product complies with Class I

Hereby declared the Apaloo GmbH, Staigstr. 9, D-78609 Tuningen, that the following products:

Product: Moskinto

Type designation: The intelligent patch

The requirements of the Directive corresponds to that set out in the following designated harmonization legislation:

93/42/EGW, changed through 98/97/EG,  
2000/70/EG, 2001/104/EG and VO (EG) 1882/2003,

References to the relevant harmonized standards that have been used, or references to the specifications for which conformity is declared:

| Field        | Titel   |
|--------------|---|
| ISO 13485    | Medical Devices Quality Management Systems Requirements for regulatory purposes |
| ISO 9001     | quality management  |
| ISO 10993-5  | Testing for the in vitro cytotoxicity   |
| ISO 10993-10 | Tests for irritation and skin sensitization                                     |
| ISO 1041     | Information supplied by the manufacturer of medical devices                     |
| ISO 15223-1  | Symbols for marking for medical devices   |
| ISO 14971    | Risk management to medical devices  |

Technical documentation with risk analysis is fully available.

The belonging to the product instructions for use is available.

This statement is made for the producer

Name: Apaloo GmbH  
Address: Staigstr. 9, D-78609 Tuningen

The sole responsibility for issuing this declaration of conformity regarding the compliance with the essential requirements and the preparation of technical documents shall be borne by the manufacturer.

Tuningen, the 24.06.2015

Place/Date

  
Andreas Jetter, CEO Apaloo GmbH