EG-Declaration of Conformity

according tot he EG directive medical devices 93/42/EGW, Annex VII

The production oft he product complies with Class I

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

Product: Kintex Kinesiologie Tape

Type designation: Classic

Teh requirements of teh Directive corresponds tot hat set out in the following designated harmonization legislation:

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

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

Field	Titel
ISO 13485:2003	Medical Devices Quality Management Systems Requirements for regulatory purposes
ISO 9001:2008	quality management
ISO 10993-1	Assessment and verification risk management process
ISO 10993-5	Testing fort he in vitro cytotoxicity
ISO 10993-10	Tests for irritation and skin sensitization
ISO 1041	Informationm 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.

Teh belonging tot he product instructions for use is available.

This statement ist made fort he producer

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

Teh sole responsibility for issuing this declaration of conformity regarding teh 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