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Konformitätserklärung / Declaration de Conformité / Declaration of Conformity / Dichiarazione di Conformita

Wir / Nous / We / Noi

Name + Adresse der Firma
Nom + adresse de l'entreprise
Name + address of the company
Nome + indirizzo della ditta

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CH-5643 Sins**

erklären in alleiniger Verantwortung, dass / déclarons sous notre propre responsabilité que /
declare on our own responsibility that / dichiariamo sotto propria responsabilità che

das Medizinprodukt
le dispositif médical
the medical device
il dispositivo medico

**Professional exercise mats S50.100:
Corona 200, Coronella 200**

Bezeichnung / nom / name / nome: Typ oder Modell
type ou modèle / type or model / tipo o modello

allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG, Klasse 1 entspricht / remplit
toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE, class 1, qui le
concernent. / meet all the provisions of the directive 93/42/EEC, class 1, which apply to him. /
addeempie a tutte de esigenze della direttiva 93/42/CEE, classe 1, che lo riguardano.

Angewandte harmonisierte oder
nationale Normen
Normes harmonisées ou
appliquées nationales
Applied harmonized or
national norms
Norme armonizzate o
nazionale applicate

- **Acute Dermal Irritation Study in Rabbits /
Harlan Lab. Study No D63815, Oct 2012
acc. to ISO 10993-10:2010 and
OECD Guideline No 404**
- **Skin Sensitization Study in Albino Guinea
Pigs - Maximization Test
Harlan Lab. Study No D63826, Nov 2012
acc. to ISO 10993-10:2010 and
OECD Guidelines No 406**
- **Determination of the antimycotic activity -
agar diffusion plate test
acc. to SN 195 921:1994**
- **Determination of the antibacterial efficacy of
treated plastic materials - germ count test
acc. to JIS Z 2801:2010**

Konformitäts-Bewertungs-Verfahren
Procédure d'évaluation de la conformité
Conformity assessment procedures
Procedimento d'evaluazione della
conformita

**93/42/EWG, Anhang 7
93/42/CEE, annexe 7
93/42/ECC, annex 7
93/42/CEE, allegato 7**

Sins, 23. Januar 2013
Ort, Datum / lieu, date
place, date / luogo, data

Dietmar Rakutt

H. Werz