EC Declaration of conformity according to the PPE Directive 89/686/EEC

We, BERNER INTERNATIONAL GMBH, herewith declare, that the following Personal Protective Equipment (PPE)

Description: Neoprene protective gloves for cytostatic

drugs and biological agents

Berner Manu Prene XP....

Specification: Sterile and non sterile

Latte Macchiato (beige) Colour:

2010, 2011, 2012, 2013, 2014, 2015, 2016, Item no.: 2017, 2018, 2019, 2020, 2021, 2022, 2023

complies with the requirements of the EC Directive 89/686/EEC for personal protective equipment and the harmonised standards:

European

DIN EN 374 part 1, 2 and 3 (2003)

 DIN EN 388 (2003) Standard:

DIN EN 420-3 (2003)

The PPE is identical with the **EC type tested one**, which was the object of the issued EC-Type Test Certificate no. PS 12050025 from the notified body 0299

DGUV Test, Testing and certification body, Technical committee for personal protective equipment, Zwengenberger Strasse 68, D-42781 Haan, Germany

Furthermore the PPE is subject to the control measures by the notified body DGUV Test (0299) in accordance with art. 11B (EC quality management system) of the EC directive 89/686/EEC.

Elmshorn, 6 February 2013

Place / Date

Dipl.-oec. Guido Maik Head of Marketing & **Product Management**





EC Declaration of conformity according to the Council Directive 93/42/EEC

We, BERNER INTERNATIONAL GMBH, herewith declare, that the following **Personal Protective Equipment (PPE)**

Description: Neoprene Protective Gloves for cytostatic

drugs and biological agents

BERNER Manu Prene XP.....

Z+8 B+8

Specification: Sterile and non-sterile

Colour: Latte Macchiato (beige)

Item nos.: 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017,

2018, 2019, 2020, 2021, 2022, 2023

in addition to the PPE-requirements in accordance with EN 420, complies with the requirements of the EC Council directive 93/42/EEC (EN 455 Parts 1-3). The quality management system in accordance to BS EN ISO 13485 is provided by the notified body.

European • EN 455-1: 2000 **Standard:** • EN 455-2: 2000

EN 455-3: 2006

(E

Notified body 0086

British Standards Institution

BSI Healthcare and Testing Services Kitemark House, Maylands Avenue

Hemel Hempstead, HP2 4SQ, United Kingdom

Elmshorn, 24 May 2012

Place / Date

Dipl.-Oec. Guido Maik Head of Marketing & Product Management

