# CE Declaration of Conformity

steriCLIN®

**We, the**

**VEREINIGTE PAPIERWARENFABRIKEN GmbH**

**Industriestrasse 6**

**91555 Feuchtwangen**

declare under sole responsibility, that our products

**See-through packaging paper and film**
*VP-code/quality* **MM70-1/PP50-1**
*Article numbers:* **3FKFB210… / 3FKSB220… / 3FKFS230… / 3FKSS230…**

**See-through packaging non-woven and film**
*VP-code/quality* **MM60-11/PP50-1**
*Article numbers:* **3FKFB240… / 3FKFS240…**

**See-through packaging Tyvek® and film**
*VP-code/quality* **TYO-3/PE62-4**
*Article numbers:* **3FKFB250… / 3FKFS250…**

are sterile barrier systems, and therefore accessories to medical devices intended by their manufacturer to be used terminally sterilized. As such, the products named above are registered as

medical devices of **class I** according to annex IX, rule 1 of the directive 93/42/EEC and amendment 2007/47/EC

and meet the basic requirements of the directive 93/42/EEC and its transposition into national laws.

The conformity assessment procedure is carried out in accordance with annex VII of the directive 93/42/EEC.
Applied standards are
**DIN EN ISO 11607 - part 1 und part 2** **DIN EN 868 - part 5**

*Any modifications to the device which are not authorized will invalidate this Declaration of Conformity.*

Feuchtwangen, 23. March 2017

VP Vereinigte Papierwarenfabriken GmbH
D-91555 Feuchtwangen · Industriestrasse 6
Fon +49 (0) 9852 901-0 · Fax -174

Heiko Brandl
Managing Director
Medical Packaging

VP Vereinigte Papierwarenfabriken GmbH
D-91555 Feuchtwangen · Industriestrasse 6
Fon +49 (0) 9852 901-0 · Fax -174

Dr. Jürgen Wirtz-Stark
Regulatory Affairs