## SPITA Smart Products B.V.

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## WARRANTY STATEMENT (medical application) ResQ-plast

We, SPITA Smart Products B.V., manufacturer of SPITA ResQ-plast self-sticking plaster/bandage, declare:

- 1) SPITA ResQ-plast is manufactured in a plant certified for the manufacturing of medical products according to ISO13485:2016 standard.
- 2) All manufacturing processes are ISO9001:2015 certified.
- 3) All regulations and protocols for hygienic production are strictly followed according to the SA8000 standard for health & safety, labor, etc.
- 4) Plant and manufacturing processes are regularly monitored under strict control of the USA Food & Drug Administration (FDA). Checks are also based on the requirements set for the manufacturing of special bandages for military use.
- 5) All material is sterilized in the manufacturing process before leaving the facility.
- 6) SPITA ResQ-plast meets and exceeds all requirements according to declaration 93/42/EEG for (self-sticking) bandages for admission on the European market (CE-marking on all packaging).
- 7) SPITA ResQ-plast complies with the EN 13726 standards for primary wound dressings, but is not intended to be used as primary wound dressing due to the general packaging of the material. When used as a primary wound bandage we RECOMMENDED the use of an appropriate disinfectant first!!
- 8) SPITA ResQ-plast is available with different compositions depending on type of skin, suffering of certain allergies, etc. (see technical datasheet for more details)
- 9) All SPITA ResQ-plast products are FREE of LATEX in order to prevent users from potential health risks.

We, SPITA Smart Products B.V., represented by Managing Director Goosen Riphagen, state that all SPITA ResQ-plast products (ResQ-plast Professional, ResQ-plast Family, ResQ-plast Sensitive, ResQ-plast Sports, ResQ-plast Clinics, ResQ-plast XL) meet the highest quality standards.

All published data and properties are based on test results complying with international standards and regularly checked by international licensed companies (UL/SGS).

International standards are used in all our technical documents and product specifications.

Harderwijk, January 2nd, 2022



Goosen Riphagen Algemeen directeur











FOOD & DRUG ADMINISTRATION USA

