

Declaration of Conformity

1. Synergie Nederland BV
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SRN NL-MF-000013839.
2. This declaration of conformity is issued under the sole responsibility of Synergie Nederland BV.
3. Basic UDI-DI as referred to in part C of annex VI: 8720387388SATGQ
- 4.



PEARLS™ (SAT2) Innovative Care



SANDS™ (SAT1) Proven Care

Air Fluidised Care Systems (AFCS) are used as a support surface for patients with a variety of medical indications. The general principle is to immerse the body in a fluid-like medium of ventilated glass beads in order to achieve near-hydrostatic pressure distribution. This results in a substantial lowering of interface pressure when compared to other types of support systems. The low relative humidity in the airflow creates an important provision to minimize infection risk and bacteria growth in the open skin. The main assemblies control unit, frame, bed and accessories will make an AFCS.

5. Risk classification: Class IIb rule 4 and rule 9
6. We herewith declare, that Air Fluidised Care Systems PEARLS™ (SAT2) and SANDS™ (SAT1) compliant to the MDR (2017/745 EU) for medical devices and the Machine Directive 2006/42/EC.

7. Notified body
DEKRA Certification (NB # 0344)
Meander 1051
6825 MJ Arnhem The Netherlands

Certificates

EN ISO 13485:2016 # 2170048

Medical devices — Quality
management systems —
Requirements for regulatory purposes

EC certificate # 2259705CE01

EU Quality Management Systems
Certificate

8. This declaration of conformity is valid from Nov - 2024

Ger Bouwens

Title: CEO



Signature:

Raamsdonksveer,

Date: 10-Dec-2024