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DEVICE

Coroplast
Coroflex Hospital 4000
Report No. CO 1509-784

DUPLICATE

Statement of
Qualification

Antibacterial Activity

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Statement of Qualification

Customer

Coroplast Fritz Müller GmbH & Co. KG
Wittener Strasse 271
42279 Wuppertal
Germany

Component tested

Category: Materials

Subcategory: Plastics

Product name: Coroflex Hospital 4000
(manufacturing date: 8/2015; color: light gray; serial number: 29-4000)

Assessment of antibacterial activity

Standards/Guidelines: ISO 22196
The norms stated generally refer to the version valid at the time of the tests.

Test environment parameters: Microbiological laboratory: S2

Test procedure parameters:

- Bacteria test:
  – defined volume of nutrient broth of *E. coli*
  – defined volume of nutrient broth of *S. aureus*
- After a period of 24 hours at an incubation temperature of 35 °C, the bacteria are transferred from the Agar plates to create a dilution series. Once the liquid cultures have been incubated, the analysis is carried out by counting the colony-forming units (CFU).

Test result / Classification

When tested using the specified suspension of bacteria, the cable sheathing material Coroflex Hospital 4000 obtained the following test result according to ISO 22196:

Antibacterial activity	Reduction factor [R]	Classification
E. coli	>4.2	excellent
S. aureus	>3.7	excellent
Overall result	**>3.7**	**excellent**

The classification is based on a worst-case scenario of the two bacterial strains used, *E. coli* and *S. aureus*. The reduction factor R is transferred to the following classification:

≥3.5 = excellent
<3.5 = very good
<3.0 = good
<2.0 = weak
<1.0 = very weak
<0.2 = none

The measuring devices used for the qualification tests are calibrated at regular intervals; their results can be traced back to national and international standards. In cases where no national standards exist, the test procedure implemented complies with the technical regulations and norms applicable at the time of the test. The relevant documentation can be viewed on request at any time.

For further information about the test environment and parameters, please refer to the Fraunhofer IPA test report.

Fraunhofer Institute for Manufacturing Engineering and Automation IPA

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Stuttgart, March 20, 2016
Place, date of first document issued

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Place, current date

on behalf of
Frank Bürger, Project Manager Fraunhofer IPA

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