MDD – Product Decision

Certificate No: 41316057-01
Date: February 25, 2019
Handled by: Beverley Oakley
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Med-Storm Innovation AS
Attn: Hanne Storm
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Purpose

Assessment of the notification dated February 20, 2019 to add additional intended uses and new functions to device included in your quality system certified according to LVFS 2003:11, Annex II (Swedish implementation of MDD 93/42/EEC).

Products concerned

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)
Skin Conductance Algesimeter	Pain Monitor	IIa	No	-

Conclusions/Decisions

The extended intended use is considered to fall within the current scope, it is still pain monitoring by skin conductance measuring, just for additional purposes.

The requested change for communcation interface to a patient monitor is also considered to fall within the scope.

The changes are accepted.

Appeals

Any appeal against this decision will be processed by an appeals panel at Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD