Guldmann™

To whom this may concern

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CVR. nr. 27 70 67 46

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Quality Statement V. Guldmann A/S

As a part of our 9001:2015 certification V. Guldmann A/S is working with continuous improvements on products as well as processes for the benefit and safety of our customers.

Our Risk Management Program ensures that we continuously improve the safety of our products when operated and used.

We comply with the EU medical Device Directive (93/42/EEC) for class I medical equipment.

Our Quality Management System conforms to ISO 13485 (Medical Mevices – Quality Management Systems – Requirements for Regulatory Purposes) and the FDA 21 CFR Part 820 (Quality System Regulation).

Four (4) times a year we receive unannounced inspections from Underwriters Laboratory (UL) in order to ensure compliance to UL requirements. Reference at UL is UL file No E305250.

Sincerely,

V. Guldmann A/S

Henrik Jensen
QA Manager