

TO WHOM IT MAY CONCERN

Your reference

Our reference

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Date

March 14, 2013

CONFIRMATION

With this letter we

B. BRAUN MELSUNGEN AG
CARL-BRAUN-STRASSE 1
34212 MELSUNGEN
GERMANY

confirm that the complete risk management process for the medical devices of the Hospital Care Division is described in a Standard Operating Procedure within the Quality Management System.

This process is in compliance with the following standard:

ISO 14971 Medical devices – Application of risk management to medical devices

For and on behalf of

B. Braun Melsungen AG

i. V.

Gudrun Henke
Senior Manager Regulatory Affairs CoE IV-Systems

i. A.

Kristin Zeyer
Administrator Regulatory Affairs CoE IV-Systems