B|BRAUN
SHARING EXPERTISE

PRODUCT COMPLAINT NUMBER: PC 500106520 (CCR 236/11)
NOTIFICATION NUMBER: 400101025
PRODUCT NAME: MONOSYN VIOLET 3/0 (2) 70CM HR26 (M)
PACK: DDP (Direct Dispense Packaging)
CODE: C0022025
BATCH: 1-8456

Based on correspondence from Regierungspräsidium Freiburg to Aesculap AG, we have to correct an error which appears on our statement, dated in July 19th, 2011.

This statement replaces the previous one sent to BfArM, in July 21th, 2011 because it have been detected some errors. Aesculap AG is the responsible manufacturer of the above mentioned product and B. Braun Surgical is the physical manufacturer of the product. Also the description of the product was not correct, it was stated Premicron whereas the correct one is Monosyn.

This is to declare that B. BRAUN Surgical with social address in Carretera de Terrassa 121, 08191 Rubí, Spain as manufacturer of sutures for the legal responsible manufacturer AESCULAP AG and trading company for Monosyn Medical Device product, in either country in the EU, and worldwide under local registration requirements, declares that a corrective action **CAPA Nº AK200457998** has been opened in order to eliminate root cause for above mentioned Product Complaint.

Root Cause: Mistake in selection Pre-printed box by Warehouse personnel. Box label and product are correct.

Following corrective actions have been planned:

a) Actions on the process:

- These boxes were labeled manually by Warehouse personnel. In order to guarantee "0 mistakes" in products that must be labeled in this manual line, a in process control person will check all products, verifying that unitary product, label match pre-printed box description as well as the corresponding reports.
  These data including the person in charge that carry out this task are collected and registered continuously
  Finished: 27/06/2011

b) Actions on the product:

- Change all probably involved boxes to the customer.
  Requested on 03/06/2011. Returned: 11/07/2011 . Status: Finished

Following preventive action has been planned to prevent recurrence:

- A new project will be developed by IT Department in order to modify warehouse program and checking that raw material involved in the manual conditioning process is the correct one.
  Status: in Course- Time scheduled: Pending.

All information quoted in this statement is reliable and evidences of the execution of the correctives actions are available upon request.

To whom it may concern, issued in Rubí, October 20th, 2011.

[redacted]
Global CT and QM/SAP Manager

[redacted]

[redacted]
BBSES Logistic and Commercial Services Manager

[redacted]

B|BRAUN B. Braun Surgical SA
Carretera de Terrassa, 121
E-08191 Rubí (Barcelona)
Spain