

Certificate

Full Quality Assurance System Approval
Annex II excluding (4) of the Directive on Medical
Devices



ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex II excluding (4) of the Directive 93/42/EEC.

This certificate is issued on behalf of:

Manufacturer

ACOPAN AG

Industriestr. 11, 9524 Zuzwil, Switzerland

ECM certifies that the full quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex II excluding (4) of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

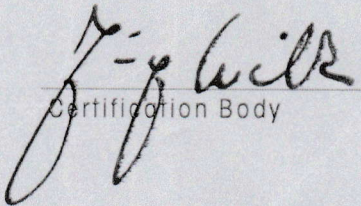
Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Audit Report Number
716-15-528

Registered under
Z/15/03654E

Valid until
September 3rd, 2020

Aachen, September 4th, 2015



Certification Body

