

EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices

Certificate Number: 2195-MED-2010002-D01

Manufacturer:

ACTO GmbH

Büchnerstrasse 11, 38118 Braunschweig GERMANY

Product(s):

Non-Sterile Wound Care Gel

Model(s):

Product Name	Packaging
Actolind w Gel	5 ml Monodose - 10 ml Monodose 5 ml - 10 ml - 30 ml - 40 ml 50 ml - 100 ml
Aclind w Gel	
SutriSept w Gel	
HydroClean Gel	

Reference Report No: MM0826-P004-R01, MM0826-P004-R02

Issued by Szutest, Notified Body 2195, this document certifies that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive.

The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

This EC Design Examination certificate is valid till 2024-05-26.

Issue Date:

2021-04-13



Rukiye BALKAN
Deputy General Manager