

EC Declaration of Conformity

The undersigned Company declares under its sole responsibility that the item of product specified below satisfies the essential requirements of the EC Medical Devices Directive 93/42/EEC with amendment 2007/47/EC directive which are apply to it.

Product Name

A solution containing the internal parts of substance which shows an activity for the Infected, dry and damaged the integrity of (chronic and acute), which are in contact with the skin on the impact of non-invasive and supportive of human activity.

Type-Models

Product Name	Package
Actolind w Solution	5 ml-10 ml-50ml-100ml-250 ml-350 ml-500 ml -1000 ml

GMDN Code

59523

Brand Name-Manufacturer

ACTO GMBH

Classification

Class III 93/42/EEC Annex IX Rule 13

Conformity Assessment Route

Annex II.4

Applicable EU Directives and Harmonized Standards

93/43/EEC Medical Devices Directive with amendment 2007/47/EC, ISO 13485, EN ISO 15223:1, EN 1041+A1, EN ISO 14971, EN 13727+A2 2016 EN 13624, EN ISO 10993-1 EN ISO 10993-1/AC, EN 10993-10, EN ISO 10993-5.2010, EN ISO 13485/AC, EN ISO 14155, MEDDEV 2.4/1 rev.9 MEDDEV 2.7/1 revision 4: MEDDEV 2.12.1 rev.8 MEDDEV 2.12/2 rev2 F1980 – 07, EN ISO 10993-3, EN ISO 10993-6, SEN ISO 10993-11 (Avrupa Farmakopesi 7)

EC Certificate No

M.2020.106.13506

Notified Body

2292 - UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş.
Mutlukent Mahallesi 2073 Sokak No:10 Umitkoy-CANKAYA

ON BEHALF OF MANUFACTURER

Name : Ahmet KILIÇ
Position : General Manager

Date-Place: 21.04.2020 / Germany

Signature-Stamp:

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