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Ackermann

EC-DECLARATION OF CONFORMITY

We the

Ackermann Instrumente GmbH

Street: Eisenbahnstrasse 65-67
ZIP: 78604
City: Rietheim-Weilheim
Ctry.: Germany

Phone: +49 (0)7461 966 17 0
Fax: +49 (0)7461 966 17 70
E-Mail: info@ackermannsurgical.com

issue as the manufacturer the present Declaration of Conformity on our sole responsibility and herewith declare self-dependently that the devices mentioned in the attached list meet the Essential Requirements as defined in Annex I MDD 93/42/EEC.

This Declaration of Conformity is issued according to Annex VII Council Directive 93/42/EEC for Medical Devices (for class I devices).

Device Group:	General Surgical Devices Device List “General Surgical Devices” on request
Classification:	Risk Class I, Rule 6 per Annex IX of Council Directive 93/42/EEC. Full list of applied standards, directives and laws on request.

Conformity Assessment has been performed under our own responsibility. The devices may therefore be placed into market labelled with

CE

This Declaration is valid for all devices listed in the Device List below until May 26, 2024.

_____

2021-04-15
PETER GRASSL
CEO

This declaration loses all validity if the Ackermann Instrumente GmbH performs a product change which affects the Conformance to the Essential Requirements or any other alteration not approved.

CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-19-576

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

Ackermann Instrumente GmbH

Eisenbahnstrasse 65-67 78604 Rietheim-Weilheim Germany

Products: Insufflator, Pedicle Screw System, Spinal Titanium Cages, Spinal PEEK Cages

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.5407.01
Date of first issue: 19 February 2019
Date of last issue: 24 May 2021
Revision Number: 06
Expiry Date: 18 February 2024

Kiwa Belgelendirme Hizmetleri A. Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

24 May 2021, Istanbul, Turkey

Kiwa Belgelendirme Hizmetleri A. Ş.
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Ackermann©
FINEST SURGICAL TECHNOLOGY

Ackermann Instrumente GmbH, Eisenbahnstr. 65-67, D-78604 Rietheim-Weilheim

To whom it may concern

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Germany

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Rietheim-Weilheim, 29.06.2023

Manufacturer declaration

We, Ackermann Instrumente GmbH, Eisenbahnstr. 65-67, 78604 Rietheim-Weilheim /Germany, hereby confirm that we comply with the Standard ISO 13402:1995-08 Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure.

Sincerely,

Ackermann©
Instrumente GmbH
Eisenbahnstraße 65-67
D-78604 Weilheim / Germany
Tel. +49-7461/966170 ; Fax 9661770

Enrico Bruno
Quality Director
Ackermann Instrumente GmbH