CERTIFICATO CE - GARANZIA DI QUALITÀ DELLA PRODUZIONE

EC CERTIFICATE - PRODUCTION QUALITY ASSURANCE

APPROVAZIONE DEL SISTEMA DI QUALITÀ ATTUATO DA
APPROVAL OF THE QUALITY SYSTEM OPERATED BY

AKTIVE S.R.L.

IT - 00173 ROMA (RM) - VIA GIACOMO DELITALA, 106

SITI / SITES

IT - 00173 ROMA (RM) - VIA GIACOMO DELITALA, 106

PER I SEGUENTI DISPOSITIVI O GRUPPI DI DISPOSITIVI / *FOR THE FOLLOWING DEVICES OR GROUPS OF DEVICES*

Strumentario e dispositivi medici per chirurgia oftalmica non attivi monouso sterili.
Strumentario e dispositivi medici per chirurgia oftalmica veicolanti prodotti e/o fluidi monouso sterili

Single-use instruments and sterile medical devices not active for ophthalmic surgery
Single-use instruments and sterile medical devices for ophthalmic surgery for products and/or fluid transfer

Certiquality S.r.l., Organismo Notificato n° 0546, certifica che il sistema di qualità
Certiquality S.r.l., Notified Body n°0546, certifies that the quality system

è conforme ai requisiti della Direttiva 93/42/CEE, Allegato V
is in compliance with the requirements of Directive 93/42/EEC, Annex

RAPPORTO DI AUDIT N° / *AUDIT REPORT NO.* **18358/1**

CERTIFICATO N. / *CERTIFICATE N.* **18358/1**

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CONCESSIONE E IL MANTENIMENTO DELL'APPROVAZIONE DI SISTEMA QUALITA' AI SENSI DELLA DIRETTIVA 93/42/CEE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE REGULATIONS FOR AWARDING AND MAINTENANCE OF QUALITY SYSTEM APPROVAL IN ACCORDANCE WITH DIRECTIVE 93/42/EEC

Il SISTEMA QUALITÀ E' SOGGETTO A SORVEGLIANZA PERIODICA
THE QUALITY SYSTEM IS SUBJECT TO PERIODICAL SURVEILLANCE

LA VERIFICA DEL SISTEMA QUALITÀ E' LIMITATA AGLI ASPETTI DELLA FABBRICAZIONE CONCERNENTI LA CONFORMITÀ AI REQUISITI METROLOGICI PER I DISPOSITIVI DI CLASSE I CON FUNZIONE DI MISURA E AGLI ASPETTI DELLA FABBRICAZIONE CHE RIGUARDANO IL RAGGIUNGIMENTO E IL MANTENIMENTO DELLO STATO STERILE PER I DISPOSITIVI DI CLASSE I STERILE.
THE AUDIT OF THE QUALITY SYSTEM IS RESTRICTED TO THE ASPECTS OF MANUFACTURE CONCERNED WITH THE CONFORMITY OF THE DEVICES WITH METROLOGICAL REQUIREMENTS FOR DEVICES IN CLASS I WITH MEASURING FUNCTION AND WITH SECURING AND MAINTAINING STERILE CONDITIONS FOR DEVICE IN CLASSE I IN STERILE CONDITION

IL PRESENTE CERTIFICATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO ALLEGATO
THIS CERTIFICATE IS NOT VALID WITHOUT THE RELEVANT ANNEX

PRIMA EMISSIONE / *FIRST ISSUE* 09/10/2012

EMISSIONE CORRENTE / *CURRENT ISSUE* 06/10/2017

DATA DI SCADENZA / *EXPIRY DATE* 05/10/2022

CERTIQUALITY S.r.l.

"LENSES GRUP" S.R.L. Nr. 1003600069

Mod. 5.20 ED 06 260517

CERTIFICATE

kiwa

Reg. Number	13704 - M	Valid From	2018-10-30
First issue date	2012-10-09	Last change date	2018-10-30
Valid until	2021-10-08		

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

AKTIVE S.r.l.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Design and production of sterile and non sterile medical devices for ophthalmic surgery
Technical assistance of own medical devices

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.
The date of issuance of this certificate is the date of first issue by another accredited body
This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

AKTIVE S.r.l.
Registered Headquarters
- Via Giacomo Delitala, 106 00173 Roma Italia

Certified Sites
- Via Giacomo Delitala, 106 00173 Roma Italia

CERMET

IAF

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 007A
SGA N° 010D
PRD N° 069B
FSM N° 004I
PRS N° 089C

REPUBLICA MOLDOVA, mun. CHIŞINĂU
"LENSES GRUP" S.R.L.
Nr. 1003600069773
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

AKtive®
Ophthalmic Instruments

00173 Roma – Via Giacomo Delitala, 106
Tel .06/88640509 – Fax 06/88384287
P.I. 09673041001
Mail info@aktive-corp.com

EC Declaration of conformity

The undersigned company AKTIVE srl manufacturer of devices:

Single-use sterile medical devices for ophthalmic surgery

Declares that every device meets all essential requirements of **Annex I of Directive 93/42/EEC** as amende by Directive 2007/47/EC, on Medical Devices.

For this purpose the manufacturer ensures and declares:

1. that every device meets the applicable provisions of Directive 93/42/EEC as amended by Directi 2007/47/EC;
2. that every device is certified according to the scheme referred to in **Annex V**
3. that the single-use devices are delivered to the market in a sterile state;
4. that the single-use devices are classified as **Class IIa;**
5. that the manufacturer undertakes to preserve and keep at the disposal of the competent authority tl technical dossier of the products for a period of at least five years after the last date of placing on tl market of the last device manufactured;
6. that the list of sterile devices related to this Declaration is attached in page 2.

The manufacturer also declares to have established and to maintain an appropriate procedure in order ensure that the post-market surveillance as required by Directive 93/42/EEC

Harmonised standards used : UNI EN ISO 13485:16 -UNI CEI EN ISO 14971:12 - UNI EN 980:09 - UNI E 1041:08 - UNI EN ISO 10993-1:12 - UNI EN 556-1:2001 - UNI EN ISO 11135-1:07 - UNI EN ISO E 11737-1:06 - EN ISO 11607-1:2009

Notified body for the annex V of Directive : CERTIQUALITY

Rome January 17, 2020

AKtive Srl
Andrea Chini
The Legal Rep.

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Via Giacomo Delitala, 106
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- AK-0231/AA - Anterior/Posterior Disposable Vitrectomy cutter 23g connector A-A
- AK-0226/AD - Anterior/Posterior Disposable Vitrectomy cutter 20G connector A-D
- AK-1717/A(S) - Phaco needle 20G 30°- disposable- set with:wrench+test chamber(NO SLEEVE)

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