



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Production Quality Assurance No. 15 0115 QS/NB

The quality system of manufacturer

Astron Dental Corporation

815 Oakwood Rd. Unit G, Lake Zurich, Illinois, 60047, USA

has been certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex V

for the following product category(ies):

Denture Base Material

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class IIb and Class III devices covered by this certificate, an EC Type-Examination Certificate according to MDD Annex III is required.

Valid from: 2020-03-03
Valid until: 2024-05-27
First Issued: 2015-03-09
Revision: c

Date: 2020-03-03



Mgr. Jiří Heš
Representative of the Notified Body No. 1023



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Annex to EC Certificate No. 15 0115 QS/NB

issued for manufacturer:

Astron Dental Corporation
815 Oakwood Rd. Unit G, Lake Zurich, Illinois, 60047, USA

Product(s):

Name:	Denture Base Material
Trade name(s):	CLEARsplint
Model(s):	LAB KIT, ECONOMY KIT, SUPER ECONOMY KIT
Class:	IIa
GMDN:	16728
Name:	Denture Base Material
Trade name(s):	CLEARsplint CAD/CAM Pro
Model(s):	ECONOMY KIT, SUPER ECONOMY KIT
Class:	IIa
GMDN:	16728
Name:	Denture Base Material
Trade name(s):	LABTEC PRO
Model(s):	ECONOMY KIT, SUPER ECONOMY KIT
Class:	IIa
GMDN:	16728



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Name: Denture Base Material
Trade name(s): LABTEC RELINE
Model(s): MINI KIT, LAB KIT
Class: IIa
GMDN: 16728

Name: Denture Base Material
Trade name(s): The Original CLEARsplint Disc
Model(s): 1 unit 95x20 with clover edge
3 unit 95x20 with clover edge
12 unit 95x20 with clover edge
1 unit 98.5x20 with shoulder
3 unit 98.5x20 with shoulder
12 unit 98.5x20 with shoulder
1 unit 98.5x20 without shoulder
3 unit 98.5x20 without shoulder
12 unit 98.5x20 without shoulder
Class: IIa
GMDN: 16728

Facility(ies):

Astron Dental Corporation
815 Oakwood Rd. Unit G, Lake Zurich, Illinois, 60047, USA

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Certificate History:

Revision	Date	Reference Number	Action
	2015-03-09	803602064	Certification
a	2018-06-29	803602706	Addition of new models
b	2019-08-29	803602807	Addition of new model
c	2020-03-03	803602829	Recertification



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