



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

EC Certificate - Full Quality Assurance System No. 15 0216 QS/NB

The quality system of manufacturer

CHIRASTAR KDT, s.r.o.

Vlnitá 52/425, 147 00 Praha 4, Czech Republic

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Dental unit chairs

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2020-04-14

Valid until: 2024-05-27

First Issued: 2015-05-22

Revision: a



Date: 2020-04-14

Mgr. Jiří Heš

Representative of the Notified Body No. 1023



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třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 15 0216 QS/NB

issued for manufacturer:

CHIRASTAR KDT, s.r.o.
Vlnitá 52/425, 147 00 Praha 4, Czech Republic

Product(s):

Name: Dental Unit Chair Bohemia 501
Trade name(s): Bohemia 501
Model(s): Mini, Ekonom, Lux, Profesional
Class: IIa
GMDN: 11165

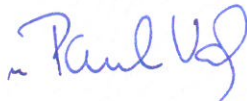
Facility(ies):

CHIRASTAR KDT, s.r.o. – office
Vlnitá 52/425, 147 00 Praha 4, Czech Republic

CHIRASTAR KDT, s.r.o. – production
Popovice 18, 250 01 Brandýs nad Labem, Czech Republic



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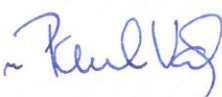
CHIRASTAR KDT, s.r.o.
Vlnitá 52/425, 147 00 Praha 4, Czech Republic

Certificate History:

Revision	Date	Reference Number	Action
	2015-05-22	803602354	Certification
a	2020-04-14	803602819	Re-certification



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