Medical Devices Book
L2-D2 Dental units

Jurisdiction / Responsibility	Operator of the practice
Model name:	
Inventory number:	

Safety Inspection / Legal regulations for the Application
For the L2-D2 dental units, regular safety inspections must be carried out in accordance with the national regulations on setting up, operating, and using of medical devices.

The test intervals result from the risk assessment to be carried out. We as the manufacturer (DKL CHAIRS GmbH) recommend a test interval of 36 months at the latest. The documentation of the test must be carried out in accordance with the national implementation of EN 62353 or corresponding national regulations.

The implementation of the safety inspection for the DKL CHAIRS L2-D2 series is shown in the DKL technician videos.

LINK: https://youtube.com/playlist?list=PLBx4baZAs6WhqPCsDXX-viqqm7qw8u1wB

Table of Contents

1. Base data

Device name / Model: _____

Serial number: _____

Inventory number: _____

CE identification no.: _____

Manufacturer: _____
(name and address)

_____

_____

Supplier: _____
(name and address)

_____

_____

Year of manufacture: _____

Device operator: _____
(name and address)

_____

_____

Location (room): _____

2. Functional test before the device is started up for the first time

Implementation date: _____

By company: _____
(manufacturer / supplier)

☐ Function check OK

☐ Operating instructions are available

Signature of the examiner: _____

3. Device instruction

3.1 Instruction of the authorized person by the manufacturer / supplier or the authorized person

Instruction takes place based on the operating instructions or the instruction protocol.

Name of instructed person (authorized person)	date	Signature of instructed person

3.2 Instructing other person / users by the manufacturer / supplier or the authorized person

Instruction takes place based on the operating instructions or the instruction protocol.

Name of instructed person / user	date	Signature instructed person	Instructor

4. Safety inspection

accordance with the national implementation of EN 62353 or corresponding national regulations

date	carried out by / company	examiner	result

Annex: safety inspection protocols

5. Maintenance measures (maintenance / inspection / repair)

date	carried out by / company	examiner	measure

6. Malfunctions or repeated operating errors of the same type

date	description of the type and sequence	registered by

7. Reporting of incidents to authorities / manufacturers

according to national regulations

An incident is a malfunction, a failure or a change in the characteristics or the performance or an inappropriateness of the labelling or the instructions for use of a medical device, which leads, could have led, or might lead directly or indirectly to the death or to a serious deterioration in the state of health of a patient, a user, or another person.

date	has been reported to	description of the occurrence