

EC DECLARATION OF CONFORMITY

Manufacturer: Audax, računalniški in industrijski inženiring d.o.o., Ljubljana,
Tehnološki park 18,
SI 1000 Ljubljana

PRODUCT: WeDoCeph
MODEL: 6
GMDN: 43187

CLASSIFICATION: I according to Rule 12 of MDD, (Annex IX)

Hereby we declare that the above mentioned product complies with the essential requirements of medical device directive 93/42/EEC. All supporting documents are retained in the premises of the manufacturer.

The product was a subject of conformity assessment procedure in Annex VII (Declaration of conformity).

The company has implemented quality management system according to the requirements of standard: EN ISO 13485:2016.

General applicable Directives:

COUNCIL DIRECTIVE 93/42/EEC; As follows, the stated product is declared as medical devices

Standards applied:

EN ISO 62304:2006; EN 62366:2008; EN ISO 14971:2012; EN ISO 15223-1:2016

Ljubljana, 15.03.2021

Audax d.o.o.
Peter Kobal