EU Declaration of Conformity

We, Ceph Assistant Kft (Budapest, Mecset u. 8, 1023, Hungary) declare under our sole responsibility as Manufacturer, that the medical device, specified in this Declaration, meets the following applicable provisions of Annex IX excluding Chapter II of Regulation 2017/745 of the European Parliament of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

EU Declaration of Conformity

Manufacturer:

Name: Ceph Assistant Kft Address: Budapest, Mecset u. 8, 1023, Hungary Street, number: Mecset u. 8, Postal code, City: H-1023 Country: Hungary
SRN: HU-MF-000059348

Medical Device that falls under this Declaration:

Name of medical device	Ceph Assistant Software
Model or type	v1.x
Description and intended purpose of medical device	Orthodontic analysis software intended for use exclusively by trained and licensed dental professionals who are qualified and legally authorized to acquire, interpret, and evaluate orthodontic and dentofacial imaging as part of clinical care.
Basic UDI-DI	59998880932AAS4
Classification	Class I, according to Rule 11, Annex VIII of Regulation (EU) 2017/745 as amended

Used Standards & other supporting documents:

EN 62304:2006+A1:2015	Medical Device Software – Software Life Cycle Processes
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Symbols to be used with medical device labels, labeling and information to be supplied
EN ISO 14971:2019	Application of risk management to medical devices
EN ISO 13485:2016+A11:2021	Medical devices — Quality management systems — Requirements for regulatory purposes
Commission Implementing Regulation (EU) 2021/2226	Laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices
Regulation (EU) 2016/679 (GDPR)	On the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
Regulation (EU) 2024/1689 (AI Act)	Laying down harmonised rules on artificial intelligence (Artificial Intelligence Act).

EU Declaration of Conformity

Signature Block:

Name:	Bendegúz H. Zováthi
Position:	Product Owner
Signature:	
Place of issue:	Budapest
Date of issue:	2026.11.02.