FOMA BOHEMIA spol. s r.o.
Jana Krušinky 1737/6, 500 02 Hradec Králové

EC DECLARATION OF CONFORMITY

CE 1014

Manufacturer:	**FOMA BOHEMIA Ltd.** **Jana Krušinky 1737/6** **500 02 Hradec Králové** **Czech Republic**
Medical Devices:	**DENTIX D** **DENTIX E** **DENTIX X-Stream**
Product type:	intraoral dental radiographic film.
Identification:	batch number on a packaging unit.
Device Classification:	Class IIa, Rule 16 (Directive 93/42/EEC, Annex IX).
GMDN Code and Term:	40978; X-ray film, diagnostic imaging, dental, non-screen.
UMDNS Code and Term:	14482; X-ray film, dental.
MD-MDS Code and Term:	MD 0401; Non-active dental equipment and instruments
Conformity with technical standards:	EN ISO 3665:2013 (specification), ISO 5799:1991 (sensitometry), manufacturer's standards PND 6-032, PND 6-036.
Quality Management System:	EN ISO 9001:2008, EN ISO 13485:2012.

FOMA BOHEMIA Ltd. hereby declares under its sole responsibility that the above listed products comply with the requirements of the 93/42/EEC Directive. The procedure according to Annex II of the Directive 93/42/EEC (Full quality assurance system) and Annex 2 of the Czech Government Order No. 54/2015 Coll. was used for CE marking. The notified body involved in the above process is *Electrotechnical Testing Institute, Czech Republic*, **Notified Body No. 1014**. EC Certificate No.: **MED 160009,** issued 2016-02-12, valid until 2021-02-11..

FOMA BOHEMIA Ltd. confirms that quality and parameters of the above listed products fulfill all relevant requirements for the products and correspond with present conditions of scientific and technical knowledge.

Ivan Tvrdík, Dipl. Ing.
Managing Director

Hradec Králové, February 9th 2018

FOMA BOHEMIA spol. s r.o. Foma 1 Hradec Králové - Czech Republic

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