



Dąbrowa Górnicza, 01.09.2023r.

Declaration of Conformity

We, Fiomex Sp. z o.o. 41-303 Dąbrowa Górnicza, Podlesie 3, Poland, hereby declare under our sole responsibility that the CE marked products of which this declaration relates:

Basic UDI-DI: 5903714204mixintipsGZ

- mixing tips „begreat”

- Yellow 5.0 mm (1:1) for impression material
- Pink 6.5 mm(1:1) for impression material
- Green 7.5 mm (1:1) for impression material
- Purple 8.5 mm (1:1) for impression material
- Blue/Orange (10:1) for temp. crown material
- Blue/White Long (1:1) 76 mm length for cement
- Blue/White short (1:1) 64 mm length for cement
- Brown/Black Short (1:1) for resin
- Brown/White Short (1:1) for cement
- Brown/White with Intraoral Tips for core
- Brown/White with Endo Tips for endo
- Dynamic Mixing Tips
- Intraoral Tips

product purpose:

mixing tips for administering materials and cements during dental procedures,

was classified as **class I, rule 5** in accordance with Regulation (EU) 2017/745 of the European Parliament and 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.

List of harmonized standards in accordance with the EU directive:

- **EN ISO 13485:2016**

The conformity assessment procedure was carried out in accordance with Annex II and III of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

The manufacturer declares that the product complies with Regulation 2017/745.