## Product Specification – TePe Toothbrushes:

TePe Select™, TePe Classic™, TePe Compact Tuft™, Implant Orthodontic Brush™, TePe Universal Care™, TePe Interspace™, TePe Graphic™, TePe Kids™, TePe Mini™

Classification:

Hygiene Product

Description:

Toothbrushes in different sizes and models

Content:

Polypropylene (PP). Polyamide (PA).

Packaging:

1 pcs/bag, 100 bags/carton 1 pcs/bag,90 bags/carton

3 pcs/blister pack 4 pcs/bag 6 pcs/bag

Others:

The wire in the toothbrushes products comply with following regulations:

EU-Directive 2011/65/EU (RoHS), 2000/53/EC (ELV), 2002/96/EC (WEEE),1907/2006/EC (REACH).

The product fulfil the criteria of being articles in line with REACH article 3 (3) and the ECHA guidance on

"Requirements for the substances in articles".

The colors are produced according to:

EU regulation 10/2011 including 321/2011, 1282/2011, 1183/2012, 2015/174.

RoHS2 directive 2011/65/EU,2015/863 (RoHS-3), 1935/2004,2023/2006 and 282/2008.

REACH Decree (EG) Nr.1907/2006

SVHC, Annex XVII EN 71part-3:2013 94/62/EC (2015/720)

The Plastic granules.

Comply with REACH Regulation.

Regulation 1935/2004/EC (Framework Regulation),2023/2006/EC (GMP).

Unionen List of Authorized Substances of Regulation 10/2011/EC.

EU Regulation 10/2011/EC. Code of Federal Regulations in 21 CFR 177.1520 (a) (1) (i) and (c) 1.1a.

FDA regulations, FCNs and 21CFR 177.1520 (b).

GB9685-2008 and Ministry of Health Announcement 2012 No.5.

FDA criteria in 21 CFR 177.1520 for food contact applications. A through H in 21 CFR 176.170 (c) Table 2,

21 CFR 176.170 (c) Table 1.

GB9685-2008 and Ministry of Health Announcement 2012No.5.

Anex II of Regulation (EU) No 1169/2011.

Regulations 1069/2009/EC, 142/2011/EC and EMEA/410/01,rev.3.

Does not contain BADGE, BFDGE, NOGE.

Regulation GMO.Metals Content according to US CONEG.

CEN standards EN71-3 / EN71-9.

VOC -LENKUNGSABAGABE, prEN 13432,prEN 13431.

This document is approved by:

Edisa Kurbegovic Quality Assurance Date vvvv-mm-dd

TePe Munhygienprodukter A Bronsåldersgatan 5 213 76 Malmö, Sweden Tel: +46 (0)40-670 11 00 Fax: +46 (0)40-670 11 11 info@tepe.com www.tepe.com



