Tech.File Summary Dental Articulating Paper GMDNS CODE 16181

1 Manufacturer

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2 Product Description

Dental Articulating Papers, Articulating Silk and Occlusion Test Foils are used in dentistry for checking occlusal contacts in static and dynamic occlusion.
Dental Articulating Papers, Articulating Silk and Occlusion Test Foils are manufactured by using different materials, thicknesses, colors and shapes (precut strips, horseshoe shape, rolls, sheets). The products are available in different package sizes.

2.1 Product Group

Based on the Global Medical Device Nomenclature (GMDN) Bausch Articulating Papers, Articulating Silk and Occlusion Test Foils can be consolidated to one group (Dental Articulating Paper GMDNS Code 16181 for external product registrations. Based on the intended use these products are comparable. The technical reference file of each subgroup is attached to this document.

Subgroup Product Detail	Reference Document (Tech.File)	GMDNS CODE
1.1 Articulating Papers 200µ	Tech.File 1.1 Articulating Papers 200µ R01	GMDNS Code 16181 Dental Articulating Paper
1.2 Articulating Papers 100µ	Tech.File 1.2 Articulating Papers 100µ R01	GMDNS Code 16181 Dental Articulating Paper
1.3 Articulating Silk 80µ	Tech.File 1.3 Articulating Silk 80µ R01	GMDNS Code 16181 Dental Articulating Paper
1.4 Arti-Check Papers 40µ	Tech.File 1.4 Arti-Check Papers 40µ R01	GMDNS Code 16181 Dental Articulating Paper
2.1 Arti-Fol 8µ	Tech.File 2.1 Arti-Fol 8µ R01	GMDNS Code 16181 Dental Articulating Paper
2.2 Arti-Fol Arti-Fol Metallic 12µ	Tech.File 2.2 Arti-Fol Metallic 12µ R01	GMDNS Code 16181 Dental Articulating Paper
2.3 Gnatho-Film 16µ	Tech.File 2.3 Gnatho-Film 16µ R01	GMDNS Code 16181 Dental Articulating Paper

2.2 Intended use

Bausch Articulating Papers and Articulating Silks are impregnated or coated papers or with different colors (color pigments). The subgroup of Occlusion Test Foils (Arti-Fol 8µ, Arti-Fol Arti-Fol Metallic 12µ and Gnatho-Film 16µ) belongs to he same group in compliance to Global Medical Device Nomenclature (GMDN), because the intended use is assimiable.

The intended use is the marking of occlusal contacts between teeth in static and dynamic occlusion on patients (invasive use) and on dental models (Dental Technician).

For marking contacts in static occlusion, thicker papers or silks with progressive color transfer are recommended. Thicker papers and silks have a higher capacity in adsorbing bigger quantities of color. This property is important for the progressive color transfer. Bausch Articulating Paper with progressive color transfer has proven to be the best in visualizing static occlusion. The sponge-like structure of the soft micro fleece paper stores the color, which is released under pressure. On heavy contacts (=greatest masticatory pressure), more color is squeezed out producing dark marks; on light contacts (=slight masticatory pressure) accordingly less color, producing light marks. To visualize contacts on saliva moistened surfaces, the contact color is optimized by adding a Transculase® bonding agent. The progressive papers therefore mark extremely well on wet, polished metal or highly glazed porcelain surfaces. Due to this specific pressure sensitive articulating paper, an exact relief of pressure distribution in habitual occlusion will be achieved. The thinner papers or Occlusion Test Film are recommended for checking the dynamic occlusion and also for marking eccentric movements.

2.3 Product Classification – Medical Product

In accordance to Council Directive 93/42/EEC Medical Devices we hereby declare that the Medical Products Class I without measuring function (Articulating Papers and Occlusion Test Films) are in conformity with the applicable requirements of the technical documentation and standards. The conformity assessment procedure is in compliance to Article 11, (5) Council Directive 93/42/EEC Medical Devices, Annex VII.

2.4 Usability according to DIN EN 62366:2008

The summary of the determination of the usability in accordance with DIN EN 62366 has proven the usability for this product group. The product fulfills the essential requirements for medical products and for the clinical use in the patients' mouth. The results of the clinical test and the simulation on dental models have proven these assumptions. The ingredients, which are used in the formulation are classified as safe non-toxic materials in accordance to biocompatibility (ISO EN 10993:1) and risk analysis in accord with DIN EN ISO 14971:2012. The application of these products by professional users is safe for the user and the patient.

2.5 Risk Management according to DIN EN ISO 14971:2012

The summary of the determination of the risk management in accordance with DIN EN ISO 14971:2012 has proven the potential risks during the usage for this product group. The product fulfills the essential requirements for medical products and for the clinical use in the patients' mouth. The results of the clinical test and the simulation on dental models have proven these assumptions. The ingredients, which are used in the formulation are classified as safe non-toxic materials in accordance to biocompatibility (ISO EN 10993:1) and risk analysis in accord with DIN EN ISO 14971:2012. The application of these products by professional users is safe for the user and the patient. Our risk management system and its documentation has been reviewed and approved by TÜV Rheinland in its function as a *Notified Body*.

2.6 Biocompatibility of Medical Devices according to DIN EN ISO 10993-1

The summary of the determination of the biocompatibility in accordance to DIN EN ISO 10993-1 has proven the potential risk during the usage for this product group. The product fulfills the essential requirements for medical products and for the clinical use in the patients' mouth. The results of the clinical test and the simulation on dental models have proven these assumptions. The ingredients, which are used in the formulation are classified as safe non-toxic materials in accordance to biocompatibility (DIN ISO EN 10993-1) and risk analysis in accord

with DIN EN ISO 14971:2012. The application of these products by professional users, are safe for the user and the patient.

2.7 Clinical evaluation of Medical Products

The clinical evaluation has been realized by Peter Bausch and Dr. Berthold Kappek in compliance with ISO 14155:2011 Clinical investigation of medical devices for human subjects -- Part 1: General requirements and MEDDEV. 2.7.1: 12-2009 GUIDELINES ON MEDICAL DEVICES – EVALUATION OF CLINICAL DATA: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES

2.7.1 Summary of clinical evaluation

Bausch Articulating Papers Articulating Silks and Occlusions Test Films are safe medical products because:

- Procedures for material inspections and measuring specifications are determinate
- Standardized procedures and test routines for biological safety have been implemented
- Investigations of relevant literature shows no potential risks using these products

The basis for a safe application is:

- Articulating Papers Articulating Silks and Occlusions Test Films should only be used by professional users (dentists, dental technicians) according to the intended use
- Adherence to safety instructions (labeled on product and/or package, instructions for use sheet)
- Potential risk caused by using the product divergent from normal use
- If allergic reactions of the patients are known then the treatment should be reconsidered.

3 Material Components

3.1 Basic Materials of subgroups

The basic materials are listed in the Tech.Files of the subgroups.

3.2 Active Ingredients of coated / impregnated color

The active ingredients are listed in the Tech.Files oft the subgroups.

3.3 Comments

All active ingredients used in our formulations are safe in those quantities exposed to the patient. All ingredients are non-hazard products. The potential risk using these products has been evaluated in the Risk Analysis (DIN EN ISO 14971:2012) and the biological safety (DIN EN ISO 10993-1) norms.
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4 Material Specifications of coated / impregnated papers, silks and foils

4.1 Standard Material Test (Final Test)

The standard material tests are described in the Tech.Files of the subgroups.

4.2 In-process-control (Random Test)

These tests are part of the validation of the manufacturing process. The frequency of these tests is in compliance with DIN 53803-2:1994-03.
The In-process-control is described in the Tech.Files oft the subgroups.

5 Manufacturing Process

The manufacturing process is described in the Annexes of the subgroups

5.1 Product Specifications

Products specifications are listed in the Annex *"Product Overview_2014.pdf "*

5.2 Impact of Medical Product

- Visible markings of occlusal contacts between the antagonist teeth when all teeth are maximum intercuspation
- Progressive marking of occlusal contacts to identify the static influence oft occlusions (static occlusal vector).
- Markings are visible on moist occlusal surfaces

5.3 Side Effect of Medical Product

Allergic reactions of the patient. The product is for about 60 years on the market. An incident with that product has never been reported (including any allergic reactions).

5.4 Other

Bausch Dental Articulating Papers, Articulating Silk and Occlusion Test Foils are used by more than 200.000 dentists in over 120 countries worldwide.
The products are manufactured in Germany in compliance with the European Medical device regulations. The Bausch company has successfully established a quality management system for medical devices (DIN EN ISO 13485:2012) which has been successfully audited and certified in October 2013 by TÜV Rheinland.

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Prepared by: Peter Bausch – General Manager

Signature: