

## **2. General Product Description**

### **2.1 Articulating Paper 200 $\mu$**

#### **2.1.1 blue BK 01, BK 1001, BK 03, BK 05**

**Name of product:** Bausch Articulating Paper with progressive color transfer blue 200  $\mu$

**Product/Order No.:** BK 01, BK 1001, BK 03, BK 05

**Description of product:**

With blue color impregnated paper-strips (200  $\mu$ ) for detection and marking of contact points on the occlusal surfaces of teeth.

The harder the bite - the darker the mark (progressive color transfer).

**Classification:**

Invasive device for transient use. Class I product according to the European Council Directive 93/42/EEC, Annex IX, Rule 5

Universal Medical Device Nomenclature System: Dental Articulation Paper (16-181)

**Technical Data:**

ingredients:	natural vegetable waxes, paraffin oil (Pharmaceutical Standard DAB 10 / Europharm 2), cellulose (Paper oxygene bleached), C.I. Pigment blue 27
color:	blue
smell:	like wax
inflammability:	flash point > 300 °C, like paper
garbage handling:	domestic waste, no special regulation is required
storage conditions:	normal room temperature, dry

**Size of paper/package:**

BK 01:	pre-cut strips 18 mm x 52 mm 300 strips per box (plastic dispenser)
BK 1001:	pre-cut strips 18 mm x 52 mm 300 strips per cardboardbox (Refill-box for plastic dispenser BK 01)
BK 03:	horseshoe shape 50 sheets per box (plastic dispenser)
BK 05:	pre-cut strips 18 mm x 104 mm, perforated twice at 46 mm / filing-margin 13 mm 3 booklets with 50 strips per cardboardbox

**General Product Description****2.1.2 red BK 02, BK 1002, BK 04**

**Name of product:** Bausch Articulating Paper with progressive color transfer red 200  $\mu$   
**Product/Order No.:** BK 02, BK 1002, BK 04

**Description of product:**

With red color impregnated paper-strips (200  $\mu$ ) for detection and marking of contact points on the occlusal surfaces of teeth.

The harder the bite - the darker the mark (progressive color transfer).

**Classification:**

Invasive device for transient use. Class I product according to the European Council Directive 93/42/EEC, Annex IX, Rule 5

Universal Medical Device Nomenclature System: Dental Articulation Paper (16-181)

**Technical Data:**

ingredients:	natural vegetable waxes, paraffinoil (Pharmaceutical Standard DAB 10 / Europharm 2), cellulose (Paper oxygene bleached), C.I. Pigment red 48:2, C.I. Pigment red 112
color:	red
smell:	like wax
inflammability:	flash point > 300 °C, like paper
garbage handling:	domestic waste, no special regulation is required
storage conditions:	normal room temperature, dry

**Size of paper/package:**

BK 02:	pre-cut strips 18 mm x 52 mm 300 strips per box (plastic dispenser)
BK 1002:	pre-cut strips 18 mm x 52 mm 300 strips per cardboardbox (Refill-box for plastic dispenser BK 02)
BK 04:	horseshoe shape 50 sheets per box (plastic dispenser)