## 0.2 DECLARATION OF CONFORMITY

#### **DECLARATION OF CONFORMITY**

MANUFACTURER:

NASCOR PTY LTD

GROUND FLOOR, UNIT 9

252 ALLAMBIE RD

**ALLAMBIE HEIGHTS** 

NSW 2100 **AUSTRALIA** 

**EUROPEAN REPRESENTATIVE:** 

VIAMED LTD

15 STATION ST

**CROSS KEYS** KEIGHLEY

YORKSHIRE

PRODUCT:

NASCOR BILIBAND™

CLASSIFICATION:

CLASS 1 ACCORDINGING TO ANNEX IX RULE 1

CONFORMITY ASSESSMENT

ROUTE:

ANNEX VII MODULE 4

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE TRANSPOSITION OF THE DIRECTIVE 93/42/EEC INTO THE LAW FOR MEDICAL DEVICES IN THE RELAVENT COUNTRIES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:

NO RELEVANT STANDARDS

START OF CE-MARKING:

13/6/01

PLACE, DATE OF ISSUE:

SYDNEY, 13/6/01

SIGNATURE:

HOWARD CHILTON MANAGING DIRECTOR



# Cohesive Stretch Bonded Laminate Bandage

### Description

Stretch Bonded Laminate (SBL) is a patented Elastic Nonwoven Fabric manufactured by Kimberly-Clark Corporation. The center layer is a "prestretched" blend of Kraton® elastomeric resin meltblown and machine direction oriented filaments, thermally bonded between two layers of 100% polypropylene spunbond-meltblown-spunbond (SMS). The center layer allows the SBL to stretch in the machine direction. The SMS layers provide strength, softness, hydrophobicity, and "stops" the stretch. The basis weight of the relaxed SBL is nominally 140 g/m²; and is approximately 40% Kraton elastomeric blend and 60% polypropylene. The SBL has an average Stretch-to-Stop (STS) of 140% where STS is defined as the maximum non-destructive elongation. The polypropylene SMS layers can be pigmented to provide color. These pigments are "colorfast" and can not be extracted from the fabric.

The SBL Fabric is re-stretched and ultra-sonically bonded to improve internal cohesion between the layers, and is spray coated on each side with 3 g/m² of a non-latex, thermoplastic, adhesive. This adhesive provides the cohesion properties of the bandage material. The Kimberly-Clark Cohesive Bandage contains no natural rubber, has been tested extensively for dermal irritation, and has been cleared by Kimberly-Clark for use as a secondary wound dressing.

### Benefits

- Contains no natural latex to avoid allergic reactions
- Self Adhesive
- Stretches up to 140% of initial length for a broad range of safe application
- . Soft and breathable for comfort
- Water resistant for cleanliness and protection
- Constant pressure for controlled compression
- Available in many colors