



MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

This is a declaration made in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the stated devices.

Manufacturers Name: Henry Schein, Inc.
Business Address: 135 Duryea Road, Melville, NY 11747 USA
Medical Device(s): Maxima Earloop Procedure Masks

Table with 2 columns: REF, Description. Rows include Maxima Earloop Procedure Masks in various colors (Green, Blue, White, Pink, Yellow, Orange, Lime Green) and Maxima Tie on masks (green, white, yellow, pink) and Maxima Tie-on Facemask Blue.

Classification: Class I
GMDN Code and term: 35177 Surgical face mask, single-use
Scope of Application: Surgical face mask
Standards Applied: AS4381:2015 (Level 2 barrier)

Each kind of medical device complies with the applicable provisions of the essential principles and the classification rules before being supplied

[Signature]
Authorized Signatory

R.P. MATHER
Name

17th July 2017
Date

Director of Special Projects...
Position