CC-JSL FOR CE FILES

FAX TRANSMISSION

NASCOR
NEONATAL
AUSTRALIA

NASCOR P/L
Ground Floor, Unit 9, 252 Allambie Road
ALLAMBIE HTS, SYDNEY TEL: +61 2 9452 6244
NEW SOUTH WALES 2100 FAX: +61 2 9958 6383
AUSTRALIA

website: http://www.nascor.com.au
e-mail: hchilton@nascor.com.au

TO: Angela, VIAMED Ltd

FROM: Howard Chilton, NASCOR

DATE: 22/11/01

RE: Biliband

Dear Angela,

The Biliband is a Class 1 medical device. It can therefore be self-declared as CE marked.

I also included the FDA Listing of it. It is exempt in the USA from the 510(k) requirement.

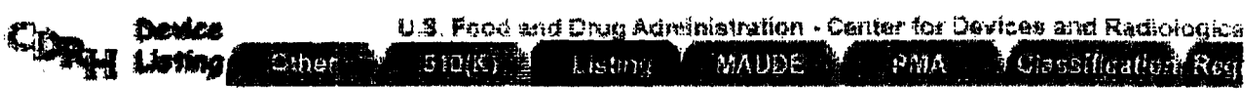
In Australia it is exempt from TGA listing as it is Class 1.

I hope this is what you customer requires.

Sincerely,

Howard

Howard



Return to Search

Proprietary Device Name:	BILIBAND
Common/Generic Device Name:	PHOTOTHERAPY EYE SHIELD
Classification Name:	PAD, NEONATAL EYE
Device Class:	1
Product Code:	FOK
Regulation Number:	880.5270
Medical Specialty:	General Hospital
Owner/Operator:	NASCOR PTY. LTD.
Owner/Operator Number:	9002451
Registered Establishment Name:	NASCOR PTY. LTD.
Establishment Registration Number:	8043571
Date of Listing:	07/17/01
Listing Status:	Active
Establishment Operations:	Manufacturer

(Database Updated November 5, 2001)
Accessibility