

Uppr.av
FRGU
Kapitel/Funktion:
MARKNAD

Godk.av
MAJO

Godk.datum
2003-10-15

Sida
1 / 1

Klass
100

Dok.nr
100235

Rev.
03

Dokumentnamn:
DECLARATION OF CONFORMITY

Declaration of conformity has been issued in accordance to the regulation of medical devices LVFS 2001:6 / appendix 7.

Dolomite AB

Box 55

S-334 21 ANDERSTORP

Hereby is declared that products below (class I-products) correspond to the directive for Medical technical equipment stated by Läkemedelsverket (Swedish Social authorities) LVFS 2001:6, and is therefore in conformity with the requirements of Council Directives 93/42/EEG, approximation of the laws of the member states relating to Technical Medical Devices as well as Swedish law 1993:584 regarding Technical Medical Devices.

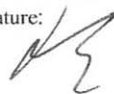
In addition, the products below (class I-products) fulfil all applicable demands in EN 12182 unless a standard of level 2 or 3 exists for a product. Such level 2 or level 3 standards are indicated in the column "Standard".

Product	Product name	Standard
12050-13	LEGACY/OPAL 2000/600	PR-EN11199-2
12052-13	LEGACY/OPAL 2000/520	PR-EN11199-2
12054-13	LEGACY/OPAL 2000/450	PR-EN11199-2
12076	DOLOMITE FUTURA 680	PR-EN11199-2
12070	DOLOMITE FUTURA 600	PR-EN11199-2
12072	DOLOMITE FUTURA 520	PR-EN11199-2
12074	DOLOMITE FUTURA 450	PR-EN11199-2
12010	DOLOMITE MELODY-L	EN11199-2
12012	DOLOMITE MELODY-M	EN11199-2
12014	DOLOMITE MELODY-S	EN11199-2
12082	DOLOMITE FUTURA 600 HP-R	PR-EN11199-2
12081	DOLOMITE FUTURA 600 HP-L	PR-EN11199-2
12084	DOLOMITE FUTURA 680 HP-R	PR-EN11199-2
12083	DOLOMITE FUTURA 680 HP-L	PR-EN11199-2
12080	DOLOMITE FUTURA 520 HP-R	PR-EN11199-2
12079	DOLOMITE FUTURA 520 HP-L	PR-EN11199-2
12160	DOLOMITE SYMPHONY 600	PR-EN11199-2
12161	DOLOMITE SYMPHONY 520	PR-EN11199-2
12162	DOLOMITE SYMPHONY 450	PR-EN11199-2
12030	DOLOMITE SOPRANO	EN11199-2
12190	DOLOMITE MAXI 650	PR-EN11199-2
12191	DOLOMITE MAXI 550	PR-EN11199-2
12220	DOLOMITE ALPHA ADVANCED	120612
12230	DOLOMITE ALPHA BASIC	120612
12350	DOLOMITE AMIGO 520	PR-EN11199-2
12360	DOLOMITE AMIGO 600	PR-EN11199-2

Declaration of Conformity according to this document is hereby signed,

Name:
Lennart Magnusson

Signature:



Date: 21/3 - 05

Position:
Managing Director / Dolomite AB

Place name:
(Anderstorp)