



Your ref: Our ref.: 380-9000/Bjorn

den 21 december 2010

As Manufacturer we confirm, under our sole responsibility, that the full Index braille embosser product line:

- Braille Embosser Basic-D
- Braille Embosser Everest
- Braille Embosser 4X4 PRO
- Braille Embosser 4Waves PRO

Bear the CE mark and comply with the following directives:

**EN14971, Risk Analysis procedure.**

**EN12182, Technical aids for disabled persons – General requirements and test methods.**

**EN 60601-1, Medical electrical equipment, Part 1: General requirements for safety.**

**EN 60601-1-2, Medical electrical equipment, Part 1: General requirements for safety – 1 Collateral standard: Electromagnetic compatibility – Requirements and test.**

**93/42/ECC, Directive for Medical Equipment**

**2002/95/EEC RoHs**

**2002/96/EEC WEE Waste Electronical and Electronic Equipment**

**ISO 9001 2008 Quality management standard**

**ISO 13485 2003 Medical Device Quality Standard**

Signed December 21- 2010

A handwritten signature in blue ink, appearing to read "Bjorn Lofstedt".

*Bjorn Lofstedt*  
Managing Director

**Index Braille AB**