

DECLARATION OF CONFORMITY «PROVIT»

D19-071

DECLARATION OF CONFORMITY «PROVIT»

We **HARALD NORDIN SA**
Z.I. La Foge
CH-1816 CHAILLY SUR MONTREUX
SWITZERLAND

declare under our sole responsibility that the product

PROVIT TEMPORARY FILLING MATERIAL
CLASS 2A, ACCORDING ANNEXE 9, DIRECTIVE 93/42/EEC

to which this declaration relates is in conformity with the following standard(s) or other normative documents

PRODUCT SPECIFICATION FOR PROVIT EST 28/11, 1997
NO ISO OR OTHER STANDARDS AVAILABLE

following the provisions of essential requirements according annexe 1, directive 93/42/EEC and/or annexe 1, directive 90/385/EEC.

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SAFETY DATA SHEET

1. Name of product: Provit Temporary Filling Material issued by

Name of Company: HARALD NORDIN SA
Z.I. La Foge
CH-1816 CHAILLY SUR MONTREUX
SWITZERLAND

2. Information on composition:

Substance which give the product its health-risk properties, if any: None
Other substances: Zincoxide, Plaster, Zincsulfate, Potassium Sulfate, Methacrylic Complex

3. Hazardous properties: None

4. First aid measures: Skin contact, eye contact: Wash with water.
Ingestion: Wait and see if less than 40 g.

5. Fire fighting measures: None

6. Accidental release measures: Pick up manually

7. Handling and storage: Store cool and dry

8. Exposure control/personal protection:

Follow the ordinary hygienic procedures common within the profession.

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SAFETY DATA SHEET

9. Physical and chemical properties:

White paste, no odour, hardens in contact with moisture.

10. Stability and reactivity: Stable when under lid, reacts with moisture.

11. Toxicological information: None

12. Ecological information: None

13. Disposal consideration: Let harden, land fill

14. Transport information: No comment

15. Regulatory information: None

16. Other information: None

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RISK ANALYSIS

1. Name of product: Provit
Class 2a, according annexe 9, directive 93/42/EEC
2. Name of company: HARALD NORDIN SA
Z.I. La Foge
CH-1816 CHAILLY SUR MONTREUX
SWITZERLAND
3. Contents: Zincoxide
Plaster
Zinculfate
Potassium Sulfate
Methacrylic Complex

All contents are well known and have been safely used in dentistry for apx. 50 years, and none have shown to be of any risk or hazard.

As main property of material is to be as inactive and inoffensive as ever possible, we see no risk for any party with this material.