



DECLARATION OF CONFORMITY

MANUFACTURER:

Technew Comércio e Indústria Ltda.

Rua Guarani, 37 – Quintino

Rio de Janeiro – RJ

Brazil

EUROPEAN REPRESENTATIVE:

Eurotechnew Comércio Imp. Exp. Material Dentário Lda

Rua do Volfrâmio, 180 – Canelas

Vila Nova de Gaia

Portugal

PRODUCT:

Calcium Hydroxide Cement

PRODUCT NAME:

Hydcal

CLASSIFICATION: Class IIa, Rule 8

ROUTE TO COMPLIANCE: Annex II, excluding section 4 of MDD 93/42 EEC as amended by 2007/47/EC

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AS AMENDED BY 2007/47/EC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

NOTIFIED BODY:

DNV GL Nemko Presafe AS, NB 2460

CE CERTIFICATION NUMBER: 10338-2017-CE-BRA-NA-PS

PLACE, DATE OF ISSUE: Rio de Janeiro, January 30th, 2018.

SIGNATURE:

Claudia Braga Ramos Vidigal
Management Representative