

Annex I



EC Declaration of Conformity

According to the Directive 98/79/EC

(Applicable to **Others/General IVD** Devices only)

Manufacturer:

Name of Company: JNC Corporation
Address: Shin Otemachi Bldg., 2-1, Otemachi 2-Chome, Chiyoda-ku, Tokyo
1008105

Product:

Device trade name: Dermatophyte Test Strip "Diafactory Tinea Unguium"
Dermatophyte Test Strip "FungiCheck Tinea Unguium"
Catalogue Number: DE001 ; Diafactory Tinea Unguium
DE002 : FungiCheck Tinea Unguium
Category: Other/ General IVDs (self-Certified)

Authorized Representative:

Name of Company: Emergo Europe
Address: Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.
Telephone/email: (phone)+31.70.345.8570, (fax)+31.70.346.7229,
(email)emergo@emergogroup.com

Conformity assessment route: Annex III, except point6, of Directive (Module A)

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

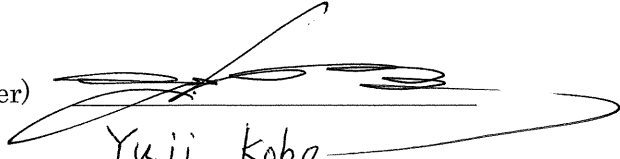
Signed on 27/(Day) 3/(Month) of 2018/(Year)

Represented by:

Signature (on behalf of the manufacturer)

Full Name of authorized signatory:

Position held in the company:



Yuji Kobo
General Manager