

**EC DECLARATION OF CONFORMITY****Nr.: 02/2016****Council Directive 93/42/EEC concerning medical devices and its amendments**Ljubljana, 22<sup>nd</sup> August 2016

Pharmadab, d.o.o., Cesta na Brdo 100, 1000 Ljubljana, Slovenija, as manufacturer of the following product

- **Medical device:** Reconval B6 cream
- **Classification:** Class I, according to classification rules reported in Annex IX
- **GMDN:** 46206

Guarantees and declares, under his responsibility, that

- The product meets the relevant provisions of *Council Directive 93/42/EEC concerning medical devices and its amendments*.
- The product meets the relevant essential requirements of Annex I to *Council Directive 93/42/EEC concerning medical devices and its amendments*.
- The product complies with the provisions of Annex VII, section 3, to *Council Directive 93/42/EEC concerning medical devices and its amendments*.
- The device doesn't incorporate substances which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC.
- The device doesn't incorporate human blood derivatives.
- The device is not manufactured utilising tissues of animal origin.
- The technical documentation referred to in Annex VII of the same Directive is kept, at manufacturer address, for a period of 5 years from the date of last production.
- Pharmadab, d.o.o. undertakes to keep up to date a systematic procedure to review experience gained, as referred to in Annex VII, section 4 of the above-mentioned Directive.
- The results of technical file and of its annex have shown that the product is safe and effectiveness relating to instructions and information supplied by manufacturer, to the environment in which the device is intended to be used, and to the expected conditions of use.

Notarka DRAGICA PAPEZ potrjuje,

ta je - so PHARMADAB, družba za farmaceutskiPharmadab d.o.o., Cesta na Brdo 100, 1000  
Ljubljana, pokrajina Anestezija Babnik- lastnoročno podpisala to listino - priznal ..... podpis na tej listini za svojo  
istovetnost imenovan le sem ugotovila: - na podlagi osebnega znanstva- z osebno izkaznico - s potnim listom št. 002332197ki jo - ga je dne 04.06.2008 izdal VE Ljubljana- s pričarji .....  
primek, ime, prebivališče

katerih istovetnost sem ugotovila

Št. OV - 1028/2016  
Ljubljani dne 23.08.2016

In faith

Pharmadab, d.o.o.  
Anastazija Babnik, MPharm.Pred overitvijo podpisa na tej listini sem notarka  
navzoče pogodbene stranke opozorila, da je  
za vsebino listine notarka odgovorna le, če v  
sestavi v obliki notarskega zapisa.NOTARSKA POMOČNICA  
VERONIKA FEGUŠ

Notarka DRAGICA PAPEŽ potrjuje,

da je to prepis originala listine - ~~overjenega prepisa~~ - navadnega prepisa listine EC DECLARATION OF CONFORMITY

Nr. 02/2016 <sup>oznaka listine</sup> z dne 22.8.2016

Listina je pisana ~~rečno~~ - na pisalni stroj - z računalnikom.

Listina ima 1 strani.

Listina je opremljena s pečatom - z žigom - s koleki

Izvirnik listine se po strankinem zahtevanju nahaja v

PH stranki

Izvirnik je stranka predložila.

V Ljubljani, dne 20.10.2017

Notarka



*Mau*

Ministrstvo za pravosodje Republike Slovenije  
potrjuje pristnost podpisa Dragica Papež  
notarke - Ljubljana

in uradnega pečata notarja Dragica Papež

Taksa v znesku 3,00 € po tar. št. 9. Zakona  
o upravnih taksah je nalepljena in uničena na zaprosilu za overitev

Št.: 0200-473/2017  
Ljubljana, 20.10.2017

KATARINA KERŠMANC  
višja svetovalka I

*Keršmanc*

Seen and certified in the  
Ministry of Foreign Affairs  
of the Republic of Slovenia

No. 020-1298/17

Date 20.10.2017

IRENA KRAPEŽ

*Irena*



ĐẠI SỨ QUÁN NƯỚC VIỆT NAM TẠI CHẾ CỐ  
EMBASSY OF THE S.R. OF VIETNAM IN THE REPUBLIC OF AUSTRIA

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ  
CONSULAR AUTHENTICATION

1. Quốc gia / Country: Việt Nam
2. do Ông (Bà) / has been signed by: IRENA KRAPEZ ký
3. với chức danh / acting in the capacity of: Viên chức Bộ Ngoại giao Slovenia
4. và còn dấu của / bears the seal/stamp of: Bộ Ngoại giao Slovenia

được chứng nhận / hợp pháp hóa lãnh sự  
Certified

5. tại / at: Viên 6. ngày / the: 27/10/2017
7. Cơ quan cấp / by: Đại sứ quán Việt Nam tại Áo
8. Số / Nº: 666 CNLS/HPHLS/2017

Ký tên và đóng dấu  
Signature and seal/stamp

Trưởng phòng Lãnh sự

*Đinh Văn Thanh*  
Đinh Văn Thanh