

Label Sample

According to Article 54. Label of medical equipment in Decree on Medical Equipment Management (36/2016/ND-CP), we submit labelling material to be used for HySil , such as the table below. All codes of HySil use the same labelling forms as specified below, we would like to replace the submission of labels for all codes by submitting representative label of one of the codes.

Label








(a): Device Name

* example of (a) section: device name



(Label Sticker)

REF ESS50HS	
Package Unit: 50ml X 4 cartridges	
Hướng dẫn sử dụng: xin xem Quyển Hướng dẫn Sử dụng ①	
 Osstem Implant Co.,Ltd. A-dong,51, Mayu-ro 238beon-gil, Siheung-si, Gyeonggi-do, Korea 15079 Tel: +82-70-4394-7896 Fax: +82-31-498-0824 ②	
Nhập khẩu và phân phối/Cơ sở bảo hành/chủ sở hữu số lưu hành : Công ty TNHH Osstem Implant Vina 326/1 Đường Nguyễn Văn Linh, Phường Bình Thuận, Quận 7, Tp. HCM ĐT: +84 28 6681 8213 ③	
Made in Korea ④	 Iu.osstem.com ⑧  Caution. Consult accompanying Documents  www.osstem.com
Số đăng ký lưu hành : ⑤	
 ⑥ LOT ⑦	

Article 54. Label of medical equipment (Decree on Medical Equipment Management)	Applicable	Location of information
(a) Name of medical equipment	A	Section (a)
(b) The registration number of free sale of the medical equipment	A	Section ⑤ in the label
(c) Name and address of the holder of the registration number of free sale of the medical equipment	A	Section ③ in the label
(d) The Origin of the medical equipment	A	Section ④ in the label
(dd) Date of production or expiry date (dd/mm/yyyy)	A	Section ⑥ in the label
(e) Number of batch or the seri number	A	Section ⑦ in the label
(g) Guidance for seeking information about warranty Provider , guidelines for using the medical Equipment, technical document serving the repair And maintenance according to regulation in Clause 2 Article 17 of this decree.	A	Section ①,③,⑧ in the label And Instruction for use (e-IFU) *Section ⑧: e-IFU symbol can be replaced by text. (ex): Hướng dẫn: Tham khảo e-IFU



Kim Han Pong