



제 13 호

[√] 의약품 [√] 제조판매 품목허가증
[] 의약외품 [] 수입

업종	의약품	업허가번호 : (업신고번호)	2286 / (구) 783
제품명	헤모크린알피(수출명:헤모크린 알피)(수출용)	분류번호	방역용 살균소독제 (07320)
원료약품(원자재) 및 분량	기허가사항과 동일	의약품분류	전문의약품
성상	기허가사항과 동일		
제조방법	별첨		
효능 · 효과	기허가사항과 동일		
용법 · 용량	기허가사항과 동일		
사용상의 주의사항	기허가사항과 동일		
포장단위	기허가사항과 동일		
저장방법 및 사용(유효)기간	기허가사항과 동일		
기준 및 시험방법	기허가사항과 동일		
제조소	자사제조, (주)휴니즈, 대한민국, 부산광역시 강서구 녹산산단 165로 22		
허가조건	기허가사항과 동일	유효기한	

「약사법」 제31조·제42조 및 「의약품 등의 안전에 관한 규칙」 제13조제1항·
제20조제2항, 같은 규칙 제59조에 따라 위와 같이 허가합니다.

2017. 2. 14

식품의약품안전처장



품목기준코드 200804324

변경 및 처분사항 등	
연 월 일	내 용
2016.02.16	원료약품변경(성분변경)/제조방법변경
2016.12.22	포장단위변경
2017.02.14	제조방법변경/수입/위탁제조원변경



EC Certificate Full Quality Assurance System: Certificate KR02/56815

The management system of

Huons Medicare Co., Ltd.

22, Noksansandan 165-ro, Gangseo-gu, Busan,
46752, Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

**Hemoclean RP for Dialyser Reprocessing;
Hemoclean for Hemodiálisis units Cleaning and Disinfection;
Hemoclean C for Hemodiálisis units Cleaning and Disinfection;
Scotelin for Endoscopes and Surgical instruments Cleaning
and Sterilant.**

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 09 February 2018 until 23 December 2022
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 01 December 2020

Issue 18. Certified since 20 September 2002

Certification is based on reports numbered WW/PCI 208135

Authorised by



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