This Report has been cleared for submission to the Director by Programme Manager, Marie O'Connor.			
Signed: Masie DConn	<u> </u>		
Environmental Protection Agency Arc Universities and Chandrade		OFFICE OF ENVIRONMENTAL SUSTAINABILITY	
	ISTER NUME	E LICENCE APPLICATION, LICENCE BER W0308-01	
FROM: DEIRDRE FRENCH		DATE: 20/10/2021	
Applicant:	Healthbeacon	Limited	
CRO number:	530689		
Location/address:	Unit 18, Naas Road Business Park, Muirfield Drive, Naas Road, Dublin 12.		
Application date:	17 November	2020	
Classes of Activity (under Waste Management Act 1996 as amen			
	operation tempor accordi in section	orage of waste pending any of the ons numbered R 1 to R 12 (excluding ary storage (being preliminary storage ng to the definition of "collection" on 5(1)), pending collection, on the site the waste is produced).	
Main BAT Note:		Note on Best Available Techniques for the Transfer and Materials Recovery – 11	
Activity description/background:	of sharps was	Ltd are proposing to accept 20 tonnes/year te (LoW Code: 18 01 03*) for bulking up for er to an appropriate waste facility.	
Additional information received:		021, 09/07/2021	
No of submissions received:	0		

Environmental Impact Assessment required:	Stage 2 Appropriate Assessment required:
No	No
Site visit (Virtually): 04/03/2021	Site notice check: 09/12/2020

1. Introduction

Healthbeacon Limited (hereafter referred to as 'Healthbeacon') is an Irish Medical Technology Company. They have developed a smart sharps container for use by patients on home injectable medication. The device reminds patients when to take their medication and tracks the disposal event. Within the smart sharps system is a replaceable sharps container where discarded sharps are contained. Traditionally this sharps container would be destroyed along with its contents. Healthbeacon are proposing to accept the sharps containers to their premises at Unit 18, Naas Road Business Park, Muirfield Drive, Naas Road, Dublin 12. The hazardous sharps waste (18 01 03*) will be transferred to a larger container and then the smaller containers will be washed, sterilised and sent back to customers for reuse.

Healthbeacon are proposing to accept and bulk 20 tonnes of hazardous sharps waste onsite per annum. The proposed activities fall below the requirement for an Industrial emissions licence (*Class 11.2: disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day*). Also, given that sharps are classified as a hazardous waste, such activities cannot be authorised by a waste facility permit. Therefore, the proposed activities require a waste licence under the Waste Management Act 1996 as amended.

The sharps waste will be stored on-site before being transferred to an appropriate waste facility for recovery. The applicant is proposing to operate the facility from 09:00 to 17:00, Monday to Friday and it will not be operational on weekends or on Bank Holidays.

2. Description of activity

The operation is proposed to be located in Unit 18, Naas Road Business Park, Muirfield Drive, Naas Road, Dublin 12 (Figure 1). The location for the proposed activities is rented by the applicant and it is proposed that the activities will be confined to the ground floor of the premises. It is located in a business park in a built-up urban area. The business park accommodates a range of other operations.



Figure 1: Location of proposed activities (Map from https://gis.epa.ie/EPAMaps/)

The proposed operations include the bulking of sharps waste (18 01 03*) for onward transport to a recovery facility. Sharps waste will be accepted onsite in UN approved sealed, rigid, 2.3 litre bins, which will be labelled to indicate that their contents are potentially infectious. Once accepted on-site, they will be brought into the processing room (see Figure 2) where they will be inspected, scanned, weighed and recorded. Waste bins arriving on-site which are ruptured or leaking will be deposited in a quarantine container before being promptly removed off-site as waste for appropriate disposal. For all other containers, the lids will be removed using a lid removal tool and the sharps waste inside deposited into a 22 litre healthcare sharps bin in the processing area. The empty 2.3 litre bin and lid will be transferred to a washing rack for the cleaning process. The bins and lids will undergo a washing process in a dishwasher type washing unit using biodegradable disinfectant. The application states that this sterilsation process will eliminate any residual microorganisms contained in the sharps bins. The application states that regular swab testing will be carried out on cleaned bins and work surfaces as part of their standard procedures.

When the 22 litre sharps bins in the processing area are full, their contents will be deposited into a larger 770 litre bin in the storage area. Then when the 770 litre bin is full, it will be sealed and collected by an authorised waste collector who will transfer the waste to an authorised waste facility. The application states that the hazardous waste will be transferred to SRCL Limited's facility (Industrial Emissions Licence ref: W0055-02) for recovery.

Sterilized polypropylene bin lids which cannot be reused will be sent for recycling. Wastewater generated during the process will be piped to a 1,000 litre bunded intermediate bulk container (IBC). Wastewater collected in this IBC on-site will be collected by an authorized third-party hazardous waste collector and disposed of at an appropriate waste treatment facility. There will be no other emissions of significance from the facility.

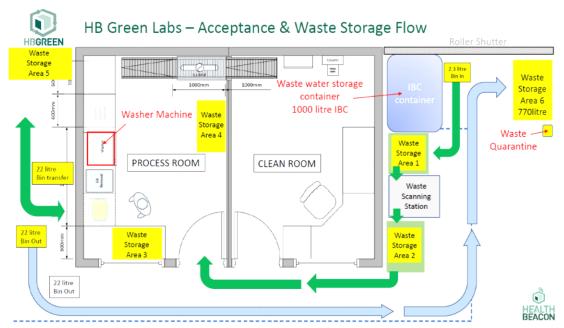


Figure 2: Layout of processing area (provided by applicant as part of application)

It is envisaged that when the site is fully operational there will be approximately 10 staff employed at the facility. The proposed activities will be confined to the ground floor of the of the building as indicated in further information received as part of the application on 09/07/2021. Schedule A.2 of the Recommended Decision (RD) sets a limit of 20 tonnes per annum on the amount of sharps waste to be accepted at the facility.

3. Planning Status

Details of these relevant planning applications and permissions have been provided in the application form.

Planning permission (Ref: 2826/20) was granted by Dublin City Council on 04/12/2020 to Healthbeacon Ltd for the development of a small-scale healthcare waste management facility. Dublin City Council considered the proposal a subthreshold development. They concluded that there are no significant effects associated with the proposed development and therefore the project was screened out for EIA.

4. EIA Screening

In accordance with Section 40(2A) of the Waste Management Act 1996 as amended, the Agency must ensure that before a licence or revised licence is granted, that the application is made subject to an environmental impact assessment (EIA), where the activity meets the criteria outlined in Section 40(2A)(b) and 40(2A)(c).

In accordance with the EIA Screening Determination, the Agency has determined that the activity is not likely to have a significant effect on the environment, and accordingly an EIA is not required.

The proposed activity is below the specified threshold of project type 11(b) in Part 2 of Schedule 5 of the Planning and Development Regulations 2001 as amended: *Installations*

for the disposal of waste with an annual intake greater than 25,000 tonnes not included in Part 1 of this Schedule.

Having considered the information provided by the applicant, which satisfies the requirements of Annex II A of the EIA Directive, it has been determined that the activity is not likely to give rise to significant effects on the environment by virtue of its nature, size or location. This determination has been made having regard to the following:

- The limited nature and scale of the activity. It is proposed to accept 20 tonnes/year of sharps waste (18 01 03*). This is significantly below the 25,000 tonnes/year threshold set out in Part 2 of Schedule 5 of the Planning and Development Regulations 2001 as amended.
- The facility is located in an industrial park. All waste handling and storage activities will be undertaken indoors. The sharps will be received onsite in 2.3 litre containers. The sharps will be temporarily stored onsite before being sent to a third party waste treatment facility.
- The empty containers will be washed and sterilised indoors. Washwater will be collected in double skinned intermediate bulk containers (IBCs) and sent offsite for treatment to an appropriate waste treatment facility.
- The activity will not generate significant dust, noise or odour emissions.
- There will be no main emissions to air from the facility.
- The stormwater runoff from the facility drains to the industrial park drainage system to the Camac River.
- There are no environmentally sensitive areas in the vicinity that are likely to be significantly affected.
- There will be limited use of natural resources. The facility will use electricity (<5kWh/annum) and water (<10m³/annum).
- The cumulative effect with other existing and/or approved projects will not be significant.

5. Best Available Techniques

I consider that the applicable BAT requirements (BAT Guidance Note on Best Available Techniques for the Waste Sector: Transfer and Materials Recovery – December 2011) are addressed through the technologies and techniques as described in the application, as well as the conditions and limits specified in the RD.

6. Emissions

6.1 Emissions to Air

This section addresses emissions to air from the facility and the environmental impact of those emissions.

6.1.1 **Channelled Emissions to Air**

There are no main emissions to air from the facility. The application refers to a minor emission point which relates to a passive vent from the wash area. The wash area consists of a domestic type dishwater which will be used for the sterilisation of the 2.3 litre containers. It is considered that any emissions from this area would not be significant.

6.1.2 **Dust**

There are no activities which will generate dust of environmental significance proposed.

6.1.3 **Odour**

There are no activities which will generate odours of environmental significance proposed.

6.2 Emissions to Water/Ground/Sewer

6.2.1 Emissions to Surface Waters

There are no direct process discharges to surface waters proposed.

6.2.2 Emissions to ground/groundwater

There are no emissions to ground/groundwater proposed.

6.2.3 Emissions to Sewer

There are no process emissions to sewer proposed. Only wastewater from the onsite canteen and toilet facilities will be discharged to the municipal sewer.

6.3 Storm water discharges

There will be no storm water discharges from the facility. All waste processing will be carried indoors within the ground floor of the building.

6.4 Noise

The main sources of noise at the facility include van/truck deliveries and collections of the waste. It is considered that these sources are not significant. Condition 6 of the RD requires the the licensee to carry out a noise survey of the site operations as required by the Agency.

7. Waste generation

Certain wastes will be generated on site as part of the licensable activity. Waste generated on site will mainly comprise of waste packaging (lids/labels), wastewater, mixed municipal waste and any damaged quarantined sharps boxes. It is estimated that approximately 10 tonnes of waste will be generated per annum.

The applicant will employ a number of measures at the facility for the prevention and/or minimisation of waste e.g. the recirculation of the clean sharps bins to customers and the recycling of clean sharps bin lids. Also, the applicant proposes to reuse undamaged

packaging. The full list of wastes and waste measures are listed in further information received by the applicant as part of the application on 09/07/2021.

8. Energy Efficiency and Resource Use

The operation of the facility involves the consumption of electricity and water. The projected water usage at the facility is $<10m^3$ /year from a public water supply.

The application states that the facility will be heated by a gas boiler, however, in correspondence received by the Agency on 01/04/2021 the applicant confirmed that there are no gas boilers at the facility and it will be heated by overhead heaters that are run on electricity. The applicant estimates that the overhead heaters will use approximately 25,460kWh of electricity per year. The applicant projects that the remaining electrical devices at the facility will consume <5 MWh per year. The applicant has proposed to employ a variety of technologies to maximise the efficient use of energy within the facility, including an efficient lighting system, use of energy efficient laptops, and optimisation of the wash cycle to minimize electricity usage.

In the application of BAT, Condition 7 of the RD provides for the efficient use of resources and energy in all site operations. It requires an energy audit to be carried out and repeated at intervals as required by the Agency and the recommendations of the audit to be incorporated into the Schedule of Environmental Objectives and Targets as outlined in Condition 2 of the RD.

9. Prevention of Accidents

A certain amount of accident risk is associated with the licensable activity. For this facility the applicant has highlighted the following potential accidents and measures for the prevention of any consequences.

Potential accidents & measures for prevention/limitation of consequences		
Potential for an accident or hazardous/ emergency situation to arise from activities at the facility	 Potential for discharge of aqueous emissions to the environment Potential for noise from the facility Potential for infection from the facility Potential for odour from the facility Potential for litter from the facility Potential for vermin Potential for fire at the facility 	
Preventative/Mitigation measures to reduce the likelihood of accidents and mitigate the effects of the consequences of an accident at the facility	 Washwater will be collected in double skinned bunded IBCs before being transported to an authorised waste facility. A spill kit and a suitably sized spill containment barrier will be provided. An Emergency Response Procedure will be in place with relevant staff trained on the procedure. 	

Condition 9 of the RD requires procedures to be put in place to prevent accidents with a possible impact on the environment and to respond to emergencies so as to minimise the impact on the environment.

In accordance with Agency Environmental Liabilities guidance¹, an Environmental Liabilities Risk Assessment (ELRA) is required to be submitted to the Agency for agreement under the Conditions of the RD (see Fit and Proper Person Assessment section for further details).

The 2019 EPA Guidance on Retention Requirements for Firewater Run-off was considered to determine the requirements for firewater retention at the facility. Given the nature and low risk of the proposed activities, it is considered that fire water retention facilities are not required at the facility.

10. Cessation of Activity

A certain amount of environmental risk is associated with the cessation of any licensable activity (site closure). For this facility the main issues upon closure will be the removal of any remaining waste from the site, and the removal of the washwater IBC offsite in a

¹ Guidance on Assessing and Costing Environmental Liabilities (EPA 2014)

manner that does not pose a risk to the environment. The applicant has provided a list of measures to be taken in the event of site closure/cessation of activity. These measures are listed in attachment 9.1.1 of the application form. Condition 10 of the RD requires the proper closure of the activity with the aim of protecting the environment.

In accordance with Agency Environmental Liabilities guidance, a costed Closure, Restoration and Aftercare Management Plan (CRAMP) is required to be submitted to the Agency for agreement under the Conditions of the RD (see Fit and Proper Person Assessment section for further details).

11. Fit & Proper Person

Technical Ability

The applicant has provided details of the qualifications, technical knowledge and experience of key personnel. The licence application also includes information on the onsite management structure. It is considered that the applicant has demonstrated the technical knowledge required.

Legal Standing

Neither the applicant nor any relevant person has relevant convictions under the the Waste Management Act 1996, as amended, or under any other relevant environmental legislation.

ELRA, CRAMP and Financial Provision

The proposed facility was assessed for the requirements of Environmental Liabilities Risk Assessment (ELRA), Closure, Restoration and Aftercare Management Plan (CRAMP) and Financial Provision (FP), in accordance with Agency guidance. Under this assessment it has been determined that ELRA, CRAMP and FP were required.

Following consultation with the OEE financial provision team it was agreed that ELRA and CRAMP may be agreed after the licence is granted. Conditions 10 and 12 of the RD requires the CRAMP, ELRA and Financial Provision be submitted to the Agency for agreement within twelve months of the date of commencement of activities.

Fit & Proper Conclusion

It is my view that the applicant can be deemed a Fit & Proper Person for the purpose of this application.

12. Submissions

There were no submissions made on this application.

13. Consultations

13.1 Cross Office Consultation

I consulted with the Office of Environmental Enforcement in relation to the ELRA, CRAMP and Financial Provision requirements and the annual enforcement charges as detailed in sections 11 and 15 of this report.

13.2 Transboundary Consultations

There were no transboundary consultations undertaken as there were no transboundary impacts identified.

14. Appropriate Assessment

Appendix 1 lists the European Sites assessed, their associated qualifying interests and conservation objectives.

A screening for Appropriate Assessment was undertaken to assess, in view of best scientific knowledge and the conservation objectives of the site, if the activities, individually or in combination with other plans or projects are likely to have a significant effect on any European Site. In this context, particular attention was paid to the European Site(s) at South Dublin Bay SAC, Glenasmole Valley SAC, Wicklow Mountains SAC, North Dublin Bay SAC, Rye Water Valley/Carton SAC, South Dublin Bay and River Tolka Estuary SPA, Wicklow Mountains SPA and North Bull Island SPA.

The activities are not directly connected with or necessary to the management of any European Site and the Agency considered, for the reasons set out below, that it can be excluded, on the basis of objective information, that the activities, individually or in combination with other plans or projects, will have a significant effect on any European Site and accordingly determined that an Appropriate Assessment of the activities was not required.

- There will be no noise, dust, water or air emissions of environmental significance from the facility.
- All activities at the facility will be carried out indoors.
- There will be no process discharge emissions to sewer.

15. EPA Charges

The annual enforcement charge recommended in the RD is \in 5,088, which reflects the anticipated enforcement effort required and the cost of monitoring.

16. Site Visit

Following the virtual site visit on 04/03/2021, it is considered that the applicant is capable of complying with the conditions set out in the RD.

17. Recommendation

The Agency, in considering an application for a licence or the review of a licence, shall have regard to Section 40 of the Waste Management Act 1996, as amended. The Agency shall not grant a licence or revised licence unless it is satisfied that emissions comply with relevant emission limit values and standards prescribed under regulation. In setting such limits and standards, the Agency must ensure they are established based on the stricter of both the limits and controls required under BAT, and those required to comply with any relevant environmental quality standard.

The RD specifies the necessary measures to provide that the facility shall be operated in accordance with the requirements of the Waste Management Act 1996 as amended and has regard to the AA Screening and EIA Screening. The RD gives effect to the requirements of the Waste Management Act 1996 as amended and has regard to submissions made.

I recommend that a Proposed Decision be issued subject to the conditions and for the reasons as drafted in the RD.

Signed

Deudic French

Deirdre French Inspector

Procedural Note

In the event that no objections are received to the Proposed Decision on the application, a licence will be granted in accordance with Section 43(1) of the Waste Management Act 1996 as amended, as soon as may be after the expiration of the appropriate period.

Appendix 1 Appropriate Assessment

List of European Sites assessed, their associated qualifying interests and conservation objectives.

Site Name	Qualifying Interests	Conservation Objectives
South Dublin Bay SAC (Site Code: 000210)	(* denotes a priority habitat) Habitats 1140 Mudflats and sandflats not covered by seawater at low tide 1210 Annual vegetation of drift lines 1310 Salicornia and other annuals colonising mud and sand 2110 Embryonic shifting dunes	As per NPWS (2013) Conservation Objectives: South Dublin Bay SAC 000210. Version 1. National Parks and Wildlife Service, Department of Arts, Heritage and the Gaeltacht.
Glenasmole Valley SAC (Site Code: 001209)	Habitats 6210 Semi-natural dry grasslands and scrubland facies on calcareous substrates (Festuco-Brometalia) (* important orchid sites) 6410 Molinia meadows on calcareous, peaty or clayey-silt-laden soils (Molinion caeruleae) 7220 Petrifying springs with tufa formation (Cratoneurion)*	As per NPWS (2021) Conservation objectives for Glenasmole Valley SAC [001209]. Generic Version 8.0. Department of Housing, Local Government and Heritage.
Wicklow Mountains SAC (Site Code: 002122)	Habitats3110 Oligotrophic waters containing very few minerals of sandy plains (Littorelletalia uniflorae)3160 Natural dystrophic lakes and ponds 4010 Northern Atlantic wet heaths with Erica tetralix4030 European dry heaths 4060 Alpine and Boreal heaths 6130 Calaminarian grasslands of the Violetalia calaminariae6230 Species-rich Nardus grasslands, on siliceous substrates in mountain areas (and submountain areas, in Continental Europe)* 7130 Blanket bogs (* if active bog) 8110 Siliceous scree of the montane to snow levels (Androsacetalia alpinae and Galeopsietalia ladani) 8210 Calcareous rocky slopes with chasmophytic vegetation 91A0 Old sessile oak woods with Ilex and Blechnum in the British IslesSpecies 1355 Otter (Lutra lutra)	As per NPWS (2017) Conservation Objectives: Wicklow Mountains SAC 002122. Version 1. National Parks and Wildlife Service, Department of Arts, Heritage, Regional, Rural and Gaeltacht Affairs.
North Dublin Bay SAC	Habitats 1140 Mudflats and sandflats not covered by seawater at low tide	As per NPWS (2013) Conservation Objectives:

(Site Code: 000206)	1210 Annual vegetation of drift lines 1310 Salicornia and other annuals colonising mud and sand 1330 Atlantic salt meadows (Glauco- Puccinellietalia maritimae) 1410 Mediterranean salt meadows (Juncetalia maritimi) 2110 Embryonic shifting dunes 2120 Shifting dunes along the shoreline with Ammophila arenaria (white dunes) 2130 Fixed coastal dunes with herbaceous vegetation (grey dunes)* 2190 Humid dune slacks Species 1395 Petalwort (<i>Petalophyllum ralfsii</i>)	North Dublin Bay SAC 000206. Version 1. National Parks and Wildlife Service, Department of Arts, Heritage and the Gaeltacht.
Rye Water Valley/Carton SAC (Site Code: 001398)	Habitats 7220 Petrifying springs with tufa formation (Cratoneurion)* Species 1016 Desmoulin's Whorl Snail (Vertigo moulinsiana) 1014 Narrow-mouthed Whorl Snail (Vertigo angustior)	As per NPWS (2021) Conservation objectives for Rye Water Valley/Carton SAC [001398]. Generic Version 8.0. Department of Housing, Local Government and Heritage.
South Dublin Bay and River Tolka Estuary SPA (Site Code: 004024)	Birds A144 Sanderling <i>(Calidris alba)</i> A157 Bar-tailed Godwit <i>(Limosa lapponica)</i> A149 Dunlin <i>(Calidris alpina)</i> A162 Redshank <i>(Tringa totanus)</i> A179 Black-headed Gull <i>(Chroicocephalus ridibundus)</i> A179 Black-headed Gull <i>(Chroicocephalus ridibundus)</i> A143 Knot <i>(Calidris canutus)</i> A192 Roseate Tern <i>(Sterna dougallii)</i> A046 Light-bellied Brent Goose <i>(Branta bernicla hrota)</i> A141 Grey Plover <i>(Pluvialis squatarola)</i> A141 Grey Plover <i>(Pluvialis squatarola)</i> A130 Oystercatcher <i>(Haematopus ostralegus)</i> A194 Arctic Tern <i>(Sterna paradisaea)</i> A193 Common Tern <i>(Sterna hirundo)</i> A137 Ringed Plover <i>(Charadrius hiaticula)</i> Habitats Wetlands	As per NPWS (2015) Conservation Objectives: South Dublin Bay and River Tolka Estuary SPA 004024. Version 1. National Parks and Wildlife Service, Department of Arts, Heritage and the Gaeltacht.
Wicklow Mountains SPA (Site Code: 004040)	Birds A098 Merlin <i>(Falco columbarius)</i> A103 Peregrine <i>(Falco peregrinus)</i>	As per NPWS (2021) Conservation objectives for Wicklow Mountains SPA [004040]. Generic Version 8.0. Department of Housing, Local Government and Heritage.
North Bull Island SPA (Site Code: 004006)	Birds A160 Curlew <i>(Numenius arquata)</i> A149 Dunlin <i>(Calidris alpina)</i> A157 Bar-tailed Godwit <i>(Limosa lapponica)</i> A162 Redshank <i>(Tringa totanus)</i>	As per NPWS (2015) Conservation Objectives: North Bull Island SPA 004006. Version 1. National Parks and Wildlife Service,

A179 Black-headed Gull (Chroicocephalus	Department of Arts,
ridibundus)	Heritage and the Gaeltacht.
A144 Sanderling (Calidris alba)	
A156 Black-tailed Godwit (Limosa limosa)	
A143 Knot <i>(Calidris canutus)</i>	
A169 Turnstone (Arenaria interpres)	
A054 Pintail (Anas acuta)	
A046 Light-bellied Brent Goose (Branta	
bernicla hrota)	
A048 Shelduck (Tadorna tadorna)	
A052 Teal (Anas crecca)	
A141 Grey Plover <i>(Pluvialis squatarola)</i>	
A056 Shoveler <i>(Anas clypeata)</i>	
A130 Oystercatcher (Haematopus ostralegus)	
A140 Golden Plover (Pluvialis apricaria)	
Habitats	
Wetlands	

Appendix 2 Relevant Legislation

The following European instruments are regarded as relevant to this application assessment and have been considered in the drafting of the Recommended Decision.

Environmental Impact Assessment (EIA) Directive (2011/92/EU as amended by 2014/52/EU) Habitats Directive (92/43/EEC) & Birds Directive (79/409/EC)

Water Framework Directive [2000/60/EC]

Waste Framework Directive (2008/98/EC)

Groundwater Directive (80/68/EEC) and 2006/118/EC

Energy Efficiency Directive (2018/2002/EU)

Environmental Liability Directive (2004/35/CE)

Appendix 3 Other CIDs/BREF/BAT documents relevant to this assessment

National BAT notes	Publication
	date
BAT Guidance Note on Best Available Techniques for the Waste Sector: Transfer and	December
Materials Recovery	2011