1. **Company**

This application relates to Howmedica International S. de R.L. trading as Stryker Orthopaedics (Company Registration Office No. 901582), a medical devices company which operates on an 18.75 acre site in the Raheen Business Park, Ballycummin, Limerick (Figure 1. Installation Location Map, at the end of this report). The plant was established at its present location in 1972 for the casting and machining of orthopaedic implants. The
company formed part of the Pfizer Corporation until December 1998, when it was acquired by the Stryker Corporation. The company’s branding and trading name changed from Stryker Howmedica Group to Stryker Orthopaedics in 2004. The company was issued its first IPPC licence (P0023-01) in 1996, and this licence was reviewed in September 2008 (P0023-02).

The company has developed and extended at the current site on a phased basis since it was established. A number of planning permissions have been granted for changes to the site since the current licence (P0023-02) was issued (September 2008), which include the addition of car parking facilities, the erection of roadside fencing, the extension of a maintenance and pump house building and the temporary installation of a portacabin.

The company operates twenty four hours a day, seven days a week and employs approximately 50 people.

Note: Licence conditions which were included in the previous licence (P0023-02) are not displayed in bold within the RD.

2. Reason for Licence Review

The licensee requested a review of the licence to accommodate a number of proposed changes at the installation. The main proposed changes include: (i) the correction of volumetric flow rates, and amendment of the emission limit values (ELVs), from the Rotary Furnace (A2-9) and Batch Furnace (A2-10); (ii) reclassification of the emissions from two Periapatite coating machines from minor to major and the addition of two new coating machines; (iii) changes to the ELVs to sewer and amendment of the monitoring frequencies, and (iv) installation of a new dust extractor and changes to the ELVs.

3. Process Description

There are three main processes in operation at the installation: (i) Recon Manufacturing; (ii) Simplex Manufacturing; and (iii) PA Coating/Biomaterials Manufacturing. The main areas affected by this review are the foundry furnaces (part of the Recon manufacturing process), the dust extractors, the Simplex powder manufacture process and the PA coating process.

The foundry furnaces operate on natural gas and are used to remove residual wax from ceramic shell moulds at ~1,090°C. The emissions from this process are passed through a high temperature afterburner to remove VOCs and particulates.

The dust extractors are used to remove dust from the metal grinding and polishing operations which follow. Dust extraction is provided by bag filters which filter the dust from the extract air and collect the dust in hoppers.

The Simplex powder manufacturing process involves a polymerisation reaction with methyl methacrylate (MMA), industrial methylated spirits, water and a catalyst. The polymer is filtered out, with the mother liquor being disposed of to a waste solvent tank. The polymer is washed several times with deionised water – the first wash is disposed to the waste solvent tank and the last two washes are discharged to sewer through SE2. The polymer is then dried and tested prior to further processing.

PA coating is a process by which hydroxyapatite (calcium phosphate) is manufactured by reacting solutions of calcium acetate and ammonium phosphate. As the hydroxyapatite is formed, it precipitates out of solution and adheres as a thin layer to the beaded surfaces of implants. The process is performed using identical coating machines. The PA coating machines have extractor fans which extract any ammonia vapours released from the process to atmosphere during the coating.

The Biotech Operations (OP-1 Implant and Osigraft Operations) and the Toolroom for the manufacture of moulds, tools and fixtures have been moved off site since the last review. This change will mean a reduction in the quantity of waste produced on-site.
4. Emissions

4.1 Air

The main emissions to air in the existing license (P0023-02) are:

- The 6 dust extractors in the main production building (A2-2 to A2-8 inclusive).
- Air emissions from the Rotary furnace (A2-9) and Batch furnace (A2-10) in the foundry.

The proposed changes to emissions to air at the installation which have a bearing on this licence review (P0023-03) are as follows:

**PA coating machines (A2-11, A2-12, A2-13 and A2-14):**

Increased production levels and the addition of two new PA machines require the inclusion of 4 main emission points to the licence (A2-11, A2-12, A2-13 and A2-14). Emission points A2-11 and A2-12 were previously minor emission points referenced as A3-10 and A3-11. The licensee has advised that the emissions from these points were measured incorrectly at the time of the last licence review and has now demonstrated that they are major emission points. A2-13 and A2-14 are new emission points from the new PA machines. The new PA machines are on-site and commissioned and process validation is on-going. The impact of the changes has been assessed in an air dispersion model as detailed later in this report.

**Dust Extractors (A2-2, A2-3, A2-4, A2-5, A2-6, A2-7, A2-8 and A2-15):**

An increase in heavy metals ELV from 0.5mg/m³ to 1 mg/m³ is sought for the dust extractor emission points. The original ELV of 0.5mg/m³ was set based on the Class II Inorganic Dust Particle emission values in BAT Note for the Manufacture of Organic Chemicals (as the emission contains cobalt). However the emission also contains chromium (Class III Inorganic Dust Particles), and as per BAT requirements, the BAT emission levels for the Class III particles are the more appropriate to use in this instance (i.e., 1mg/m³). Changes to the maximum volumes to be emitted from each emission point have also been requested, and the minimum discharge heights have been changed based on recent stack measurements. The impacts of these changes have been assessed in an air dispersion model, discussed later in this report.

The licensee carried out emissions monitoring to identify the suit of metal parameters (and concentrations) present in the emissions from the installation. The monitoring identified two metals listed under Class II inorganic dust particles (i.e., cobalt and nickel) and two metals listed as Class III inorganic dust particles (i.e., Chromium and Manganese) and other metal particulates. The RD specifies BAT ELVs, as detailed in the Guidance Note of Best Available Techniques for the Manufacture of Organic Chemicals, for both Class II and Class III inorganic compounds from the relevant emission points. As specified in the BAT note, the RD includes a requirement for the sum of Class II and Class III emissions not to exceed the ELV specified for Class III inorganic compounds.

A new dust extractor (A2-15) has been added, which is currently being commissioned. The dust extractor associated with emission point A2-6 has been moved off-site but will be returned and re-commissioned at to the installation at a future, currently unknown, date. The dispersion model carried out included the emissions from A2-15 and A2-6.

**Rotary Furnace (A2-9) and Batch Furnace (A2-10):**

An increase in the volumetric flow limits for emission point A2-9 (Rotary Furnace) from 14,000m³/d (700m³/hr) to 120,000Nm³/d (5,000m³/hr) is proposed to reflect actual flow volumes from this emission point (incorrect volumes were reported to the Agency during the previous licence review). For the same reason, an increase in the volumetric flow limits for emission point A2-10 (Batch Furnace) from 1,200m³/d (200m³/hr) to 120,000Nm³/d (5,000m³/hr) is requested.
As per the dust extractor emission points, the licensee requests an increase in the heavy metal concentration ELV to 1mg/m³, in line with the BAT emission levels for Class III Inorganic Dust Particles. As stated previously the RD specifies a limit for both Class II and Class III Inorganic Dust Particles. In addition, the minimum discharge height for A2-9 has been increased from 7m to 9.1m. Due to the correction of the volumetric flow rates for A2-9 and A2-10, no maximum mass emissions rate is specified for these emission points.

While the previous licence placed an ELV on VOCs from both furnaces, the licensee states that given the high temperatures in the furnace, the potential for VOCs to be present is negligible and that the control of TOC at these emission points is more representative. An ELV of 50mg/m³ is included in the RD for TOC in-line with the BAT emission levels for this sector.

A heat recovery system will be added to the Rotary furnace (A2-9) for space heating and hot water purposes. Hot air from the main furnace exhaust flue will be extracted through a branch flue. The branch flue will contain an isolation damper, heat recuperator and fan to overcome the additional resistance of heat recovery components. To attain temperatures suitable for the heat recuperator, the exhaust gas is required to be cooled with ambient air before reaching the heat recuperator. Exhaust from the heat recovery branch will be emitted through a new main emission point (A2-16). The proposed heat recovery is predicted to significantly reduce the energy required for water and space heating requirements at the installation.

The impact of all the changes detailed above has been assessed in an air dispersion model as detailed below.

Four new minor emission points are being added to the site:
- A3-17 will arise from a new Final Intermediary Cleanline (FIC), an ultrasonic cleaner used to clean medical device parts prior to final packaging and dispatch. Steam will be exhausted from this emission point.
- A3-18 is associated with the PA Dissolution Line, a new automated enclosed process designed to remove PA coating from parts, releasing negligible levels of NOx.
- A3-19 belongs to a new condensing boiler which will provide heat for the new centralised Air Handling Units. The boiler has a heat output capacity of 540kW.
- A3-20 is the emission point for the new gas fired steam generator which will be used for the filter dryer vessels in the Simplex powder manufacture area.

There are no changes proposed to any of the existing minor emission points (A3-2, A3-5, A3-6, A3-7, A3-8, A3-9, A3-12, A3-13, A3-14, A3-15, A3-16), the other boiler emissions (A1-1 – A1-6) or the fugitive emission points (A4-1, A4-2 and A4-3) as part of this review.

Impact of Air Emissions on Receiving Environment
The licensee completed air dispersion modelling of the emissions from the installation, including the proposed changes to the emissions described, using US EPA approved AERMOD Prime model. The model was run using meteorological data from Dublin Airport from 1996 to 2005 and building wake effects were considered in the model. The modelled Ground Level Concentrations (GLCs) represent the maximum single predicted 1-hour concentration, 24-hour concentration and annual average concentrations, where appropriate, for the specific parameters.

Background air quality for total suspended particulates was incorporated in the dispersion model from representative Zone C sites. A background concentration of zero was assumed for metals, dioxins/furans and ammonia, as sources of these parameters are rare. A background value of zero was also selected for TOCs as there is no routine monitoring of TOC in the Limerick area and data from other Zone C sites was not considered representative. Terrain data has not been included in the model as examination of the geophysical data in the area of the Stryker facility shows that the
facility lies in a relatively flat area within the Shannon flood plain and is considered simple terrain.

The model incorporated all major emission points at the installation. The parameters modelled included individual metals (including chromium, cobalt, manganese and nickel) TOC, dioxins/furans, ammonia, total particulates, PM$_{10}$ and PM$_{2.5}$. The model assumes a worst case emissions scenario for the majority of parameters in terms of discharge loadings and operating hours. As there are no emission limit values set for individual metal compounds, the licensee modelled the average of actual monitored individual parameter emission concentrations. The concentration limits and mass emission limits used in the model are BAT values for certain parameters for this sector (and TA Luft values in the case of Dioxins/Furans). The monitoring results have shown that the actual emission levels are generally well below these limits. The volumetric flow rates used are based on design levels.

The highest predicted GLCs arising for each modelled parameter were then compared with the relevant air quality standard, guideline value or environmental assessment factor.

No detailed risk assessment analysis for dioxins/furans involving a determination of TDI (Tolerable Daily Intake) has been undertaken in this assessment. A screening risk assessment was carried out assuming that all dioxins/furans remain in the vapour phase and the predicted GLCs were compared to the annual average European urban background for context.

Results of Atmospheric Dispersion Modelling

Table 1 below shows the predicted maximum GLCs of compounds based on the modelling assessment compared to the relevant standards set in legislation and literature.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Modelled Impact Averaging Period</th>
<th>Maximum Predicted Ground Level Concentration (including background concentration) $\mu g/ m^3$</th>
<th>Air Quality Standard/ Guideline Value/ Environmental Assessment Level $\mu g/ m^3$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Particulates</td>
<td>Annual Average</td>
<td>121</td>
<td>150</td>
</tr>
<tr>
<td>PM$_{10}$</td>
<td>24-hour</td>
<td>15.83</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>Annual Average</td>
<td>15.81</td>
<td>40</td>
</tr>
<tr>
<td>PM$_{2.5}$</td>
<td>Annual Average</td>
<td>10.0</td>
<td>25</td>
</tr>
<tr>
<td>Chromium</td>
<td>99%ile 1-hour mean</td>
<td>2.02</td>
<td>150</td>
</tr>
<tr>
<td></td>
<td>Annual Average</td>
<td>0.09</td>
<td>5</td>
</tr>
<tr>
<td>Cobalt</td>
<td>99%ile 1-hour mean</td>
<td>0.146</td>
<td>1</td>
</tr>
<tr>
<td>Manganese</td>
<td>99%ile 1-hour mean</td>
<td>0.17</td>
<td>1,500</td>
</tr>
<tr>
<td></td>
<td>Annual Average</td>
<td>0.007</td>
<td>0.15</td>
</tr>
<tr>
<td>Nickel</td>
<td>Annual Average</td>
<td>0.016</td>
<td>0.02</td>
</tr>
<tr>
<td>Total Organic Carbon (TOC)</td>
<td>Annual Average</td>
<td>16.3</td>
<td>800</td>
</tr>
<tr>
<td>Dioxins/Furans</td>
<td>Annual Average</td>
<td>$2.5 \times 10^{-9}$</td>
<td>-</td>
</tr>
<tr>
<td>Ammonia</td>
<td>24-hour</td>
<td>20.3</td>
<td>2,500</td>
</tr>
<tr>
<td></td>
<td>Annual Average</td>
<td>1.23</td>
<td>180</td>
</tr>
</tbody>
</table>
Discussion of Modelling Results
The results of the atmospheric dispersion modelling show that the maximum GLCs generally occur at the north eastern boundary of the installation. As shown in Table 1 above, the results of the modelling show that the GLCs will be significantly below the relevant air quality standard, guideline value or environmental assessment level for all modelled substances.

For dioxins and furans the worst case emissions from the Stryker installation (based on the maximum emission rate at the proposed ELV (maximum rate of 1.5µg/hour)) are predicted to contribute less than 5% of the urban ambient background (assuming a background of 50fg/m³). Therefore dioxin risks are considered to be very low.

The model indicated that the operation of the four perlapatite coating machines emitting at the BAT emission level for Ammonia (30mg/m³) will have a negligible impact to atmosphere and will not have an adverse impact on the nearby Loughmore Commons Turlough pNHA (Site Code 000438), located 400m west of the site boundary.

The predictive modelling incorporated several worst-case assumptions and thus is considered to have over-estimated the actual impact of emission from the installation. In conclusion, no adverse environmental impact is envisaged to occur at, or beyond the site boundary whilst operating the installation at full capacity. On the basis of the modelled results and the controls specified in the RD the emissions to air from the installation, at the ELVs specified in the RD, will not have a significant impact on the environment. Schedule C.1.2 of the RD specifies the monitoring requirements in relation to the emissions to air from the installation. These require the licensee to monitor the key parameters annually to verify compliance with the specified ELVs.

Monitoring:
Condition 4.1.2(iv) of the existing licence (P0023-02) require that the mass flow threshold rates and mass flow limits are determined on the basis of a single 30 minute average concentration. In order to better reflect the emissions occurring over the full process cycles of the furnaces and PA machines, the licensee proposes that the emissions concentrations are monitored over the full process cycle and that mass flow thresholds are determined as an average concentration over the process cycle multiplied by the measurement of flow. The duration of the process cycles are 60 minutes for the rotary furnace; 12hrs for the batch furnace and 6 hours for the PA coating machines. It is considered that monitoring over process cycles of significant duration would have significant implications for Agency compliance monitoring from both a time and cost perspective. Condition 4.1.2(iv) of the RD has been amended to provide for a 60 minute monitoring period.

The licensee proposes that the standard conditions for oxygen in combustion gases, as stipulated in Condition 4.2, i.e., 3% oxygen for liquid and gas fuels and 6% oxygen for solid fuels, are expanded to take account of the oxygen levels in each furnace's flue gases, i.e., 16% oxygen for the Rotary Furnace and 18% oxygen in the Batch Furnace. The information provided to support this request shows that the Rotary Furnace is designed to operate at 11% oxygen and the Batch Furnace at 8% oxygen. Both furnaces have been modified since they were originally installed (with the manufacturers approval) to allow the addition of further oxygen, which facilitates better burn-off and improved product quality. The exact quantity of oxygen added varies depending on production activity and furnace load. Therefore, to ensure emission monitoring data is reported based on oxygen levels which are consistent across all operating conditions, and that the emissions to atmosphere specified in this licence are achieved without the introduction of dilution air, the standard conditions for oxygen in Condition 4.2 have been amended to the design levels of 11% for the Rotary Furnace and 8% for the Batch Furnace. While the BAT guidance for this sector does not specify oxygen levels in this instance, the changes are consistent with BAT for other sectors.
4.2 Emissions to Sewer

This licence review does not significantly amend the proposed emissions to sewer from the installation. The majority of process effluent from the facility discharges to sewer at SE1. This effluent is treated prior to discharge by pH balancing and neutralization in an underground tank equipped with agitation and pH monitoring and control. The sewer is part of the Limerick City and Environs agglomeration which was granted discharge licence D0013-01 on the 13/8/09, and has a waste water treatment plant at Bunlicky with a design capacity of 130,000 population equivalent (p.e.). The agglomeration p.e. is approximately 110,000 p.e. and therefore there is considered to be adequate capacity in the waste water works.

Due of the addition of two new PA machines, an increase in ELVs for a number of parameters in the emissions to sewer at SE1 is proposed. These changes include the following:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Existing Concentration ELV (mg/l)</th>
<th>Existing Mass Emission ELV (kg/day)</th>
<th>Proposed Concentration ELV (mg/l)</th>
<th>Proposed Mass Emission ELV (kg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Ammonia (as N)</td>
<td>300</td>
<td>40</td>
<td>1,300</td>
<td>60</td>
</tr>
<tr>
<td>BOD</td>
<td>500</td>
<td>80</td>
<td>3,000</td>
<td>150</td>
</tr>
<tr>
<td>COD</td>
<td>1,000</td>
<td>140</td>
<td>6,000</td>
<td>250</td>
</tr>
<tr>
<td>Chlorides</td>
<td>800</td>
<td>200</td>
<td>3,000</td>
<td>250</td>
</tr>
</tbody>
</table>

Changes to the monitoring frequency for certain parameters are also proposed as follows:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Existing monitoring frequency</th>
<th>Proposed monitoring frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Suspended solids</td>
<td>Weekly</td>
<td>Monthly</td>
</tr>
<tr>
<td>Nitrates</td>
<td>Weekly</td>
<td>Monthly</td>
</tr>
<tr>
<td>Total Phosphorus (as P)</td>
<td>Weekly</td>
<td>Monthly</td>
</tr>
<tr>
<td>Chlorides</td>
<td>Weekly</td>
<td>Monthly</td>
</tr>
<tr>
<td>Oils, Fats, Grease</td>
<td>Weekly</td>
<td>Monthly</td>
</tr>
</tbody>
</table>

The Water Services Authority has given consent for the changes proposed and these have been incorporated into the RD. The toxicity limit specified in the previous licence is retained.

The effluent from the Simplex powder process lines (after the mother liquor and first wash from these lines are disposed of separately as hazardous waste) as well as the laboratory washings, canteen facilities and toilet discharges are discharged through SE2. No effluent treatment is undertaken at present on this discharge except for the use of sink waste interceptors and grease traps for the canteen effluent. A pH neutralisation station is proposed to be installed on the SE2 discharge line to neutralise the Simplex effluent discharge before it combines the foul sewer and canteen discharges. The RD requires the licensee to notify the Agency when the neutralisation tank is installed on SE2.

The licensee has also requested an increase in the SE2 emission volume limit, from 10m³/day to 100m³/day, to accommodate possible future changes at the installation. The Water Services Authority (WSA) consent under Section 99E related to 10m³/day. The licensee has not assessed the impact of this proposed increase on the receiving WWTP. Where the WSA agrees to an increase in the volume limit from SE2 this may be submitted to the Agency for consideration, however, issues in relation to BAT, energy efficiency and the impact on the municipal WWTP will need to be considered.

4.3 Emissions to Waters

There are no process emissions to water from the installation.
4.4 Surface Water

Surface water arises from the run-off from buildings, car-parks, roadways, service yards and other developed areas of the site which discharge to the main Raheen Business park storm water system at three emission points: SW1, SW2 and SW3. Surface water from the Raheen Business Park discharges to the Loughmore Common canal (NHA Site Code 000438), which enters the Barnakyle stream, which in turn flows into the Maigue River and subsequently the River Shannon (both rivers being in the Lower River Shannon SAC (Site Code 002165) and River Shannon and River Fergus SPA (Site Code 004077)). A stage 1 Screening for Appropriate Assessment was submitted as part of the licence application and the screening concluded that the activity will not have a significant effect on any Natura site and that an Appropriate Assessment was not required.

There is currently one oil separator at SW1. Plans and designs have been developed for four additional oil trap separators (Class I full retention and by-pass separators) at the installation, to ensure that all storm water passes via an appropriate separator. These works were to be carried out under Condition 3.8 of the existing licence (P0023-02) but have not yet been completed. The requirement to install silt trap and oil separators for storm water discharges via SW1, SW2 and SW3 has been retained in the RD.

All chemical storage areas are provided with spill containment facilities. Firewater retention penstock valves are installed on two of the three surface water discharge points. Should an accidental spill of chemicals occur on-site that has the potential to enter the surface water run-off from the site, then the penstock valves can be closed to contain the contaminated liquid. The liquid can then be analysed and disposed of through appropriate waste disposal methods and routes. A Firewater Retention Report was submitted to the Office of Environmental Enforcement (OEE) under Condition 3.9 of the existing licence (P0023-02) and was agreed by the Agency. In a letter dated 12th March 2012, the OEE instructed the licensee to submit a proposal for the construction of a firewater retention pond, or similar retention system, on-site. This proposal has been agreed, subject to a full design specification being submitted. Condition 3.9 of the RD has been amended to include this provision. The condition also provides that the fire-water retention risk assessment is reviewed and updated as required by the Agency.

4.5 Emissions to Ground

There are no emissions to soil or groundwater from the installation.

4.6 Waste

There are no significant changes to the waste types generated on site. Wastes include machine oils/coolants, metal dust collected in dust collectors, metal and plastic swarf/turnings, lapping oil and colloidal silica, nitric acid waste, off-specification Simplex Powder, scrap powder containing antibiotic, laboratory solvents. Hazardous waste is drummed and stored in the Waste Chemical store pending collection by approved waste contractors. Non-hazardous waste awaiting collection is stored in a compound which has an isolation valve and oil interceptor/containment tank to remove any oil residue from water run-off and enable contaminated water in the compound to be collected for analysis and treatment if necessary. The conditions of the RD provide for the control of off-site waste disposal and recovery.

4.7 Noise

The licensee proposes to move the existing noise monitoring locations (AN1-AN7), which are positioned at locations along the site boundary, to positions on the north, south, east and west corners of the site boundary (AN-8 to AN-11). A Noise Sensitive Location (NSL1) is also proposed at the South Court Hotel.

The site is located in a business park, near a busy public roadway. The main sources of noise at the installation arise from the operation of the dust extractors at the rear of the
site. Noise monitoring reports also attribute the extraneous vehicle noise as sources of noise at the boundary locations.

The existing monitoring locations (AN1 to AN7) and the proposed new monitoring locations (AN8 to AN11 and the proposed NSL) were monitored in September 2010. On the basis of the data provided, it is considered that AN8 to AN11 will adequately represent boundary noise conditions, in place of AN2 to AN7. However as tonal noise was identified at AN1 during the a previous monitoring event, it is considered that AN1 should remain as a monitoring location. As the site is located in a business park, and as the nearest NSL is a hotel which is impacted predominately by noise from the nearby public roadway, it is considered that noise limits should be applied to the boundary monitoring locations only and that a NSL monitoring point will not be required.

The ELVs for noise are set out in Schedule B.4. of the RD. In accordance with the EPA document Guidance Note for Noise: Licence Applications, Surveys and Assessments in relation to Scheduled Activities (NG4) (2012), the day time ELV has been changed from 55dB $L_{Aeq}$ to 55dB $L_{A,T}$ (1) to allow for corrections for tonal noise, and an evening time ELV has been introduced.

Based on the monitoring data provided, it is noted that noise levels at AN8 to AN11 exceed the noise ELVs. The licensee attributes this to significant extraneous noise from vehicular activities outside the site, with the dust extraction units on-site, the air cooler and vehicular movements within the site also identified as noise sources. No noise complaints have been received by the licensee or the EPA.

An investigation of noise sources at the boundary locations AN1 to AN7 was carried out under the existing licence (P0023-02). The main noise sources and mitigation measures were identified in a Noise Report dated May 2009. Various measures were put in place between May and Sept 2009 which reduced tonal noise.

Condition 2 of the RD includes a requirement for the licensee to evaluate noise reduction measures under the Schedule of Environmental Objectives and Targets. In addition Condition 6.14 of the RD requires the licensee to undertake remedial action as necessary to ensure compliance with the specified noise limits.

---

1. $L_{A,T}$ being a rated noise level, which is the noise level equal to $L_{Aeq}$ during a specified time frame (T) plus a specified adjustment (5dB penalty) for tonal character and/or impulsiveness of the same. During the night time, no tonal or impulsive noise should be audible, so $L_{Aeq}$ values apply in that instance.

5. Use of Resources

There is no significant change in the use of resources with regard to this licence review. Electricity and natural gas are the major sources of energy used on site. In 2010 a total of 12,130 MWhr of electricity and 732,457m$^3$ of natural gas were used on site. Gas is used in the Rotary furnace, the Batch Furnace, plant boilers, 23 roof mounted air handling units and the laboratories. The major users of electricity on site include the dust collectors, foundry inductotherm power pack units and the vacuum furnaces.

In 2010, a total of 46,391m$^3$ of water was used on site from the town water main supply and 3,277m$^3$ of groundwater was taken from the on-site well.

Raw material usage will not change as a result of the changes made on site, with the exception of the expected decrease in natural gas usage following the installation of the heat recoverer associated with new emission point A2-16.

6. Climate Change Impact

With regard to reducing the Climate impact of the installation under IPPC, the RD requires an energy efficiency audit and an assessment of resource use efficiency. An energy audit was completed for the site in the last year. A number of specific energy reduction projects have been identified, including installation of a heat recovery system, which are
now included in the EMP. The EMP objectives and targets include use of cleaner production (including production related carbon footprint).

The licensee does not have or require a Green House Gas (GHG) Permit in accordance with the European Communities (Greenhouse Gas Emissions Trading) Regulations 2004, (S.I. No. 437 of 2004 as amended).

7. Compliance with EU Directives


This installation falls within the scope of Category 4.1(h) of Annex I of Council Directive 2008/1/EC concerning integrated pollution prevention and control.

The IPPC directive requires that the competent authority take account of the general principles set out in Article 3 when determining the conditions of a permit. The Recommended Determination (RD) as drafted takes account of the requirements of the Directive. In particular **Condition 7**, Resource Use and Energy Efficiency, provides conditions dealing with water, energy and raw material use, reduction and efficiency on site and **Condition 10**, Decommissioning Management provides for decommissioning of the site following cessation of the activity.

It is noted that the Howmedica International S. de R.L. trading as Stryker Orthopaedics activity/activities fall under Category 4.1(h) of the Industrial Emissions Directive (IED) (2010/75/EU).

BAT for the installation was assessed against the **BAT Guidance Note on Best Available Techniques for the Manufacture of Organic Chemicals (1st Edition – August 2008)**.

7.2 Air Quality Directive 2008/50/EC and 2004/107/EC

As outlined above, dispersion modelling of emissions to air was undertaken for the application, which indicated that emissions from the installation will not cause any breaches of relevant Air Quality Standards as specified in S.I. No. 180 of 2011 and/or S.I. No. 58 of 2009.


The existing licence required an Environmental Liabilities Risk Assessment (ELRA) and Residuals Management Plan (RMP). These reports have been submitted to the OEE and are under assessment. The RD includes a requirement to review these on an annual basis and submit the results in the AER.

7.4 Water Framework Directive [2000/60/EC]

There are no process emissions to surface or groundwater from the installation. The impacts of process effluent emissions to sewer are discussed in Section 4.2 of this report.

7.5 European Communities Environmental Objectives (Surface Water) Regulations, S.I. No. 272 of 2009

There are no process emissions to surface waters from the installation.

7.6 European Communities Environmental Objectives (Ground Water) Regulations, S.I. No. 9 of 2010

Abstraction of groundwater is covered by these regulations. The Stryker site is in the area of the Limerickurban_sw (IE_SH_G_146) Ground Water Body (GWB). The GWB is at ‘poor’ status for chemical issues (phosphate), but is at ‘good’ status for abstraction issues as it has no significant abstractions. The EPA's Office of Environmental Assessment (OEA) has commented that the abstraction of groundwater from the on-site well at the current rate (approximately 20% of the total supply) is not likely to have an impact on the WFD status of this GWB.

7.7 Groundwater Directives (80/68/EEC) and 2006/118/EC
There are no process emissions to groundwater from the installation.


Surface water run-off from the site discharges to the surface water collection system in Raheen Industrial Park. This water eventually discharges to the Lower River Shannon SAC (Site Code 002165) and the River Shannon and River Fergus SPA (Site Code 004077), which are located approximately 3km north of the plant. The Curraghchase Woods SAC (Site Code 000174), Tory Hill SAC (Site Code 000439) and Askeaton Fen Complex SAC (Site Code 002279) are all within a 15km radius of the site.

A screening for Appropriate Assessment was undertaken to assess, in view of best scientific knowledge and the conservation objectives of the site, if the activity, individually or in combination with other plans or projects is likely to have a significant effect on the European Sites.

The screening assessment undertaken demonstrates that the activity is not likely to have significant effects, in terms of maintaining favourable conservation status of the qualifying interests, on the European Site(s) having regard to its conservation objectives. It is considered that due to the design of the surface water drainage system and the accident and emergency response procedures in place on site, it is highly unlikely that any significant emissions could discharge to the surface water drainage system and therefore, no significant potential impacts are anticipated in relation to the Lower River Shannon SAC and the River Shannon and River Fergus SPA as a result of the installation operations. In addition, the remaining SACs are considered to be at a sufficient distance from the plant with no connecting pathways (e.g., rivers or streams) for indirect effects to occur. It is therefore not anticipated that there will be any likely significant impacts on these sites.

In accordance with the European Communities (Birds and Natural Habitats) Regulations 2011 (S.I. No. 477 of 2011), pursuant to Article 6(3) of the Habitats Directive, the activities will not adversely affect the integrity, in terms of maintaining favourable conservation status of the qualifying interests of the European Site(s), having regard to its conservation objectives.


An Environmental Impact Statement (EIS) was not submitted with the application.

The Agency has considered the application and has determined that the licence application should be made subject to an EIA as respects the matters that come within the functions of the Agency.

The licensee was requested to submit an EIS to the Agency accordingly and this EIS was received on 6th March 2013.

I have considered and examined the content of the EIS and other material (information submitted in the licence application, correspondence between the Agency and the planning authority carried out under Section 87(1I) of the EPA Acts and submission made by a third party in relation to the EIS (addressed in Section 14.1 of this report)). I consider that having examined the relevant documents and with the addition of this Inspector’s Report that the likely significant direct and indirect effects of the activity have been identified, described and assessed in an appropriate manner as required in Article 3 and in accordance with Articles 4 to 11 of the EIA Directive as respects the matters that come within the functions of the Agency. I consider that the EIS also complies with the EPA (Licensing) Regulations 1994, as amended.

Environmental Impact Assessment (EIA)

An EIA, as respects the matters that come within the functions of the Agency, has been carried out in accordance with Section 83(2A) of the EPA Acts, as detailed below.
Consultation was carried out between Limerick County Council and the Agency in accordance with Section 87(11)(f) of the EPA Acts. The submissions and observations exchanged between Limerick County Council and the Agency have been considered as part of this assessment. Limerick County Council made comments in relation to EIS, all of which related to the discharge to sewer from the installation.

As some of the comments in the Section 87(11)(f) response conflicted with the Section 99E, as approved by Limerick County Council in October 2012, clarification was sought from Limerick County Council (14/05/2013). A response was received on 19/06/2013, which clarified that Limerick County Council had no objection to the licence conditions as originally approved by way of the Section 99E consent received in October 2012.

One third party submission/observation was received which was relevant to impacts on the environment which has been considered and taken into account.

The submitted EIS and the assessment as described in this Inspectors Report address the likely significant direct and indirect effects arising from the activity, as respects the matters that come within the functions of the Agency.

### Likely significant effects

The following section identifies, describes and assesses the main likely significant direct and indirect effects of the proposed activity on the environment, as respects the matters that come within the functions of the Agency, for each of the following factors: human beings, flora, fauna, soil, water, air, climate, the landscape, material assets and cultural heritage. The main mitigation measures proposed to address the range of predicted significant impacts arising from the activity have also been outlined.

#### 1. Human Beings

<table>
<thead>
<tr>
<th>Likely significant effect</th>
<th>Description of effect</th>
<th>Mitigation measures proposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emission to atmosphere</td>
<td>Potential impacts due to elevated environmental concentrations</td>
<td>See table 5 below</td>
</tr>
<tr>
<td>Noise from operation</td>
<td>Potential noise nuisance</td>
<td>See table 5 below</td>
</tr>
</tbody>
</table>

#### 2. Flora & fauna

<table>
<thead>
<tr>
<th>Likely significant effect</th>
<th>Description of effect</th>
<th>Mitigation measures proposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact of storm water discharges</td>
<td>Storm water impact on water quality</td>
<td>See table 4 below</td>
</tr>
</tbody>
</table>

#### 3. Soil

<table>
<thead>
<tr>
<th>Likely significant effect</th>
<th>Description of effect</th>
<th>Mitigation measures proposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>No significant effects</td>
<td></td>
<td>-</td>
</tr>
</tbody>
</table>

#### 4. Water

<table>
<thead>
<tr>
<th>Likely significant effect</th>
<th>Description of effect</th>
<th>Mitigation measures proposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact of storm water discharges</td>
<td>Storm water impact on water quality</td>
<td>Installation of an additional oil separator at SW-3</td>
</tr>
</tbody>
</table>

#### 5. Air
### Emission to atmosphere

- Potential impacts due to elevated environmental concentrations of parameters emitted to atmosphere
- Use and maintenance of appropriate air emissions abatement (e.g., particulate filters, afterburner on furnaces to reduce VOC and dust emissions)
- Installation meets BAT
- ELVs, abatement controls, and monitoring requirements for emissions to air specified in the RD

### Noise from operation

- Potential noise nuisance for local residents and environmental receptors
- Acoustic insulation to control/reduce noise
- Noise limits and noise monitoring requirements specified in the RD

### 6. Climate

<table>
<thead>
<tr>
<th>Likely significant effect</th>
<th>Description of effect</th>
<th>Mitigation measures proposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>No significant effects</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 7. Landscape, Material Assets & Cultural Heritage

<table>
<thead>
<tr>
<th>Likely significant effect</th>
<th>Description of effect</th>
<th>Mitigation measures proposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resources usage</td>
<td>Depletion of resources</td>
<td>Use of energy efficient equipment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Energy efficiency audit and resource use efficiency requirements specified in the RD</td>
</tr>
</tbody>
</table>

**Assessment of parts 1 to 7 and the interaction of effects and factors**

The detailed assessment set out before this section of the Inspector’s Report fully considers the range of likely significant effects of the activity on human beings, flora, fauna, soil, water, air, climate, landscape, material assets and cultural heritage, as respects the matters that come within the functions of the Agency, (as identified in parts 1-7 above), with due regard given to the mitigation measures proposed to be applied. The Planning Authority provided additional observations to the Agency under Section 87 of the EPA Acts.

A matrix of the potential significant interaction of impacts is provided in Table 15.1 on page 55 of the EIS.

I have considered the interaction between the factors referred to in parts 1-7 above and the interaction of the likely effects identified (as well as cumulative impacts with other developments in the vicinity of the activity). The EIS identifies mitigation measures to address identified potential significant interactions.

I am satisfied that proposed mitigation measures are adequate. I do not consider that the interactions identified are likely to cause or exacerbate any potentially significant environmental effects of the activity. The RD includes conditions as considered appropriate to address the key interactions associated with the licensable activity.
Overall Conclusion on EIA Assessment

All matters to do with emissions to the environment from the activity, the licence application documentation and EIS have been considered and assessed by the Agency. The assessments carried out by the planning authority and the submissions and observations exchanged between the planning authority and the Agency have been considered as part of this assessment.

I consider that having examined the relevant documents and with the addition of this Inspector’s Report that the likely significant direct and indirect effects of the activity have been identified, described and assessed in an appropriate manner as required in Article 3 and in accordance with Articles 4 to 11 of the EIA Directive, as respects the matters that come within the functions of the Agency.

It is considered that the mitigation measures as proposed and the licence conditions included in the RD will adequately control any likely significant environmental effects from the activity.

9. Cross Office Liaison

Information in relation to the licensee’s compliance with the current licence was provided by Maria Lenihan, Linda Dalton and Martin O’Reilly of the Office of Environmental Enforcement. Information with regard to groundwater issues was provided by Matthew Craig and Donal Daly in the Office of Environmental Assessment.

10. Best Available Techniques (BAT)

I have examined and assessed the application documentation and I am satisfied that the site, technologies and techniques specified in the application and as confirmed, modified or specified in the attached Recommended Decision comply with the requirements and principles of BAT. I consider the technologies and techniques as described in the application, in this report, and in the RD, to be the most effective in achieving a high general level of protection of the environment having regard - as may be relevant - to the way the facility is located, designed, built, managed, maintained, operated and decommissioned.

11. Fit & Proper Person Assessment

The Fit & Proper Person test requires three elements of examination:

- Technical Ability
- Legal Standing
- Financial Standing

The most recent Environmental Liabilities Risk Assessment review report, submitted by the licensee, was approved by the OEE in February 2013. The financial provisions mechanism is yet to be finalised.

It is my view, and having regard to the provisions of Section 84(5) of the EPA Acts and the conditions of the RD, that the licensee can be deemed a Fit & Proper Person for the purpose of this Review.

12. Compliance Record:

The licensee has operated under IPPC Licence Reg. No. P0023-02, since the 11th September 2008, with minor issues of non-compliance. The Office of Environmental Enforcement (OEE) carried out a site inspection of the activity on the 27th March 2012. A non-compliance was issued for exceedance of ELVs at SE1 (for COD in particular). An increase in the SE1 ELVs is being sought as part of this licence review. There have been no convictions under the EPA Acts or other relevant legislation.

13. Complaints

No complaints have been received in relation to the site by either the licensee or the EPA.
14. **Submissions**

One submission was received in relation to this application.

14.1 **Submission from An Taisce** - Ian Lumley, Built Environment and Heritage Officer, received 19th April 2013

The submission received from An Taisce relates to the Environmental Impact Statement associated with this licence review application. The submission states that the Court of Justice of the European Union Case 50-09 needs to be addressed with regard to the application through:

1. The requirement of the EPA as a consent authority to perform an Environmental Impact Assessment, and
2. The requirement to integrate the EIA for the IPPC licence application with all other planning and other consents applicable to the installation.

*Comment:* - The EPA has carried out an EIA, as respects the matters that come within the functions of the Agency, in accordance with Section 83(2A) of the EPA Acts. This assessment is documented in the EIA section of this report, above.

As mentioned previously, it is considered that the mitigation measures as proposed and the licence conditions included in the RD will adequately control any likely significant environmental effects from the activity.

15. **Recommended Determination (RD)**

In preparing this report and the Recommended Determination I have consulted with Agency technical and sectoral advisors. The RD as drafted includes a range of conditions that have been developed to afford protection to the surrounding environment.

I am satisfied that the conditions as set out in the RD will adequately address all emissions from the installation and will ensure that the carrying on of the activities, in accordance with the specified conditions, will not cause environmental pollution.

16. **Charges**

The annual enforcement charge included in the RD is €11,860.96, which is considered appropriate for the enforcement effort required. No significant change in enforcement is envisaged as a result of this licence review.

17. **Recommendation**

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

Signed

[Signature]

Stuart Huskisson

**Procedural Note**

In the event that no objections are received to the Proposed Determination of the application, a licence will be granted in accordance with Section 87(4) of the Environmental Protection Agency Acts 1992 and 2013 as soon as may be after the expiration of the appropriate period.
Figure 1. Installation Location Map: Howmedica International S. de R.L Trading as: Stryker Orthopaedic - P0023-03